Deposition of Lee P. Bendel Taken on
January 22 (Case No. 97-550-SLR)

HL

476

In The Matter Of:

CORDIS CORPORATION v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.

LEE P. BENDEL
January 22, 1998

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Original File lb012298.v1, 134 Pages
Min-U-Script® File ID: 1786277668

Word Index included with this Min-U-Script®

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)
Plaintiff,) 97-550
vs.)
ADVANCED CARDIOVASCULAR)
SYSTEMS, INC. GUIDANT CORPORATION,)
ARTERIAL VASCULAR ENGINEERING,)
INC.; BOSTON SCIENTIFIC CORPORATION)
and SCIMED LIFE SYSTEMS, INC.,)
Defendants.)

VIDEOTAPED DEPOSITION OF LEE P. BENDEL
New York, New York
Thursday, January 22, 1998

Reported by:
ROBERT X. SHAW, CSR
CSR NO. 817
JOB NO. 64439

January 22, 1998
9:53 a.m.

Videotaped Deposition of LEE P. BENDEL, held at the offices of Dewey Ballantine, LLP, 1301 Avenue of the Americas, New York, New York, pursuant to Notice, before Robert X. Shaw, CSR, a Notary Public of the State of New York.

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THE VIDEOGRAPHER: This is tape number 1 of the videotaped deposition of Mr. Lee P. Bendel taken by the defendants in the matter of Cordis Corporation plaintiff versus Advanced Cardiovascular Systems Inc. and Guidant Corporation, defendants in the United States District Court for the District of Delaware, number 97-550.

This deposition is being held at the law offices of Dewey Ballantine, 1301 Avenue of the Americas, New York, New York on January 22, 1998 at approximately 9:53 a.m.

My name is Marcelo Rivera from the firm of Esquire Video Services, and I am the Legal Video Specialist.

The court reporter is Robert Shaw, in association with David Feldman & Associates, 216 East 45th Street, New York, New York.

Will counsel please introduce themselves.

MR. BAILEY: Craig Bailey of Fulwider Patton Lee & Utecht for the defendant Advanced Cardiovascular Systems.

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MR. NAGY: John Nagy of Fulwider Patton Lee & Utecht, for Advanced Cardiovascular Systems.

MR. GELERNTER: Gene Gelernter from Patterson Belknap, for the plaintiff.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

L E E BENDEL, called as a witness, having been first duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION BY
MR. BAILEY:

Q: Would you please state your name for the record.

A: Lee P. Bendel.

Q: What is your address?

A: My address is 25003 Pinewater Cove Lane, Bonita Springs, Florida.

Q: Where are you currently employed?

A: I have a consulting firm that we call Materials Technology Associates.

Q: Were you a founder of that firm?

A: Yes.

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Q: Were you the sole founder?

A: My wife and I are the founders of the firm.

Q: Are there any employees in the firm besides yourself?

A: Yes, there are.

Q: How many others?

A: Currently we have one other.

Q: Who is that individual?

A: That individual is Marlene Flanagan.

Q: What's the nature of the business of Materials Technology Associates?

A: We do consulting work in the area of medical products and in the area of specialty stainless steels and some technical assistance conducting tests on surgical products.

Q: What kinds of medical products has Materials Technology Associates been involved with?

A: Surgical needles, staples, stapling devices, ligating devices, stents, and I think that is the extent of it.

Q: Would the order in which you named them represent the relative amounts of work that

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the company has done, in other words, you have done the most with needles, then followed by staples and the least with stents?

A: No. I think it is, the mix is probably fairly equal.

Q: Between all four categories that you have named?

A: Yes.

Q: What's your wife's position in the company?

A: She is the president of the company.

Q: Does your company do any consulting for Johnson & Johnson or any of its subsidiaries or affiliated companies?

A: Some of the work that we have done had been for Johnson & Johnson companies.

Q: All right. What percentage of the work of Materials Technology Associates has been for Johnson & Johnson or its related companies?

A: Probably a fairly large percentage, about 80 percent.

Q: Has any of the work been for Cordis?

A: Yes. It has.

Q: What percentage of the work has been

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for Cordis?
MR. GELERNTER: Time frame?
MR. BAILEY: Well, let's say in the past year.
A: In the past year? A fairly small percentage has been for Cordis. I actually suggested that they create their own testing laboratory and I talked myself out of a job with them.
Q: How long has Materials Technology Associates been in business?
A: Just about three years now.
Q: In the first two years, did you do any greater percentage of work for Cordis?
A: Yes. I did.
Q: What percentage would it have been in the first two years?
A: Oh, it might have been 30 or 40 percent at that time. I am really giving rough estimates here. I did not -
Q: Fair enough. Is it fair to say that any of the technical work that would have been performed by Materials Technology Associates for Johnson & Johnson or its related companies would

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have been performed by you personally?
MR. GELERNTER: Objection to form.
Any of the technical work performed by Cordis, is performed by him?
Q: I misspoke then.
I meant any of the technical work performed by Materials Technology Associates for Johnson & Johnson or its related companies has been performed by you personally?
A: Some of it has been performed by me personally. Others by some of the technicians that are or were in our employ.
Q: Who were those technicians?
A: I mentioned Marlene Flanagan. Fay Varley. Marie Sabecky, Ruth Donnelly and Elke Lindemann.
Q: Would those individuals have been working under your direction?
A: Actually, in some cases, yes, but not all.
Q: Could you describe for me in general terms the nature of the work that Materials Technology Associates has done for Cordis over the three years of its existence?

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A: We provided assistance in the area of testing of stents, reviewing the results that were conducted on stents, reviewing some of the manufacturing processes that are associated with the production of stents.
Q: What kind of testing would you have done?
MR. GELERNTER: Objection to form. You can answer.
A: Primarily -
Q: What kind of testing did you do?
A: Primarily scanning electron microscope examinations. I also arranged to have done work to evaluate the corrosion resistance of stents that are subjected to in vitro fatigue testing.
Q: What does in vitro mean?
A: Not in the body. I had to think about the definition there between in vivo and in vitro.
Q: What was the purpose of the SEM examinations that you conducted?
A: To review the stent expansion characteristics, to review the effect if there was any of high-cycle long-time fatigue testing

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on the stents.
Q: You also indicated that you reviewed some results of some stents; I am not quite sure what you meant by that?
A: Well, that was a matter of where after fatigue testing was completed some photographs were taken by a trained scanning electron microscopist using a protocol that I had developed, and then the photographs were supplied to me to interpret.
Q: These were photographs the stents?
A: Correct.
Q: What was the condition of the stents that were being photographed?
A: These were stents that had been subjected to, well in some cases it was stents before they were subjected to the fatigue testing and then the same stent after it was subjected to fatigue testing.
Q: So the purpose of this review was to evaluate the fatigue characteristics of these stents?
A: Yes.
Q: Aside from what you have just

described to us have you, you or your company, done any other sort of tests or evaluations of stents?

MR. GELERNTER: Aside from his work in this case.

Q: Aside from your work in this case, yes. Let's put that aside for now.

A: Okay. I did mention when you asked generally what I do.

I said that I reviewed some of the manufacturing processes, reviewed the process used by the tubing supplier of the stent material using my knowledge as a metallurgist familiar with stainless steels to ensure jointly with the Cordis quality assurance people that good manufacturing processes were being utilized to make the stent tubing.

Q: Anything else?

A: Similarly for the laser cutting process.

Q: Anything else?

A: Not that I can recall right now.

Q: All right.

A: Some others may come to mind, but not

right at this moment.

Q: Over the three years that your company has been doing work for Cordis, can you estimate for me how much Cordis has paid you for the work?

MR. GELERNTER: Objection to form.

A: For the total three years?

Q: The total. I am looking for the grand total, yes.

A: Oh, gosh. Probably over 10,000, less than 50,000.

Q: Apart from your work on this lawsuit are you still doing consulting work for Cordis?

A: I did something late last year for Cordis in the area of the corrosion testing that I discussed.

But the work that I have done for Cordis this past year has been, has been minimal because as I said I suggested to them that they have people in-house, get people in-house who have the training and background that I have.

Q: The work that your company did for the Johnson & Johnson Companies as a group, if I could refer to them as that, how much income have

you derived from that work over the three years that Materials Technology Associates has been in existence?

A: When you say how much income, are you talking about a net to me or gross?

Q: I mean how much has Technology Materials Associates received from the Johnson & Johnson companies?

A: Well, I want you to help me a little bit here.

Q: Sure. I will be pleased to do that.

A: If I arranged to have a firm that is expert in the area of doing MRI testing to do some testing and that testing cost $5,000 and I billed J & J for that testing, I have gotten $10,000 for that testing but I have passed it straight through.

Q: Understood.

A: So...

Q: If you are able to separate the two, go ahead and do that. In other words, the gross amount you have received and if you can separate out past through charges, please do that as well.

A: In light of the fact that I worked on my income tax very recently, our gross for 1987, excuse me, 1997 was $160,000.

Q: All right.

A: My wife and I pay each other a salary of $12,000 a year. We have a pension profit sharing plan in the company, where we put in 25 percent of that, and our profit this past year was about $10,000.

So, our direct financial benefit was in the neighborhood of $40,000 total for all of the work that I did. I am semi-retired, so.

Q: Of this $160,000 gross, does that include these past through charges that you have mentioned?

A: Yes. Yes, it does. All of the past through charges, my travel expenses when I go to Taiwan, whatever else.

Q: And what percent of this 160,000 would have been derived from work that you did for the Johnson & Johnson companies?

A: Probably 75 or 80 percent.

Q: Would those gross revenue figures and those percentages be similar for the first two

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years of Materials Technology Associates' existence?

A: Yes. I think they would.

Q: What's your educational background after high school?

A: I have a bachelor's degree in metallurgical engineering from Lehigh University, it was awarded in 1962. And I have a master's degree also from Lehigh University also in metallurgical engineering and that was awarded in 1966.

Q: Where were you employed prior to your affiliation with Materials Technology Associates?

A: Prior to Material?

Q: Yes. Prior to.

A: Very briefly with a company called Metal Tech Alloys. And I am not even sure that I list that on the CV.

I was a silent partner in the business. The company makes solder and custom jewelry metal, and I was primarily an investor and thought I might want to be active in it and was only involved as an employee for a very brief period of time. And then prior to that I was

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with Ethicon for approximately 24 years.

Q: And Ethicon is a subsidiary of Johnson & Johnson?

A: You know, I don't know if subsidiary is the right legal business term for it, but Ethicon is certainly a part of Johnson & Johnson.

Q: Fair enough. And Material, excuse me, Metal Tech Alloys, did they do any work for Johnson & Johnson while you were with them?

A: Yes. I did some consulting for Johnson & Johnson and I billed that work through Metal Tech Alloys.

Q: What kind of work did you do for Johnson during that period of time?

A: It was identical as to what I had done as Materials Technology Associates.

Q: Did you retire from Ethicon?

A: Yes. I did.

Q: Are you receiving any sort of retirement benefits from that company?

A: Yes, I am.

Q: Do you own any stock in Ethicon?

A: In Ethicon?

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Q: Yes.

A: No.

Q: In Johnson & Johnson?

A: Yes. I do.

Q: If you could just briefly trace for me the positions that you held throughout your time at Ethicon.

A: Okay. I was hired there the end of September, the beginning of October of 1969 as a senior, I think my title might have been needle development metallurgist.

And from around 1969 to, the hiring date, until about 1976, I worked in the research division and I think I got some promotions from metallurgist to senior to group leader to supervisor.

In 1976 I transferred to the Manufacturing Department, and there I was the manager of Wire Drawing and Specialty Operations.

Q: If I could go back for a second. You said your first position was in needle development. Are we talking about hypodermic needles?

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A: No.

Q: What kind of needles were they?

A: We are talking about surgical needles. Have you had stitches?

Q: I can't say that I have.

A: You are fortunate, but I am sure that someone in this room has and that's what we are talking about here.

Q: Very good. And then when you moved over into manufacturing you said wire Drawing and Specialty Operations.

A: Yes.

Q: Were those things that were affiliated with the needle product line?

A: Yes. They were.

Q: And then how long were you in that position?

A: Approximately four years.

Q: Until 1980?

A: Yes. It might have been the very end of 1979 or '80, I don't remember the exact dates.

Q: What position did you take next?

A: Then I came back into the technology

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section, in what was the Engineering Division as the manager of I guess it was called needle - development metallurgy.

Q: And we are still talking about the surgical needles?

A: That is correct.

Q: How long were you in that role?

A: I was in that role for, let's see, from 1980 to '92 - about 12 years.

Q: And then what position did you hold?

A: And then I was promoted to a position called senior engineering fellow.

Q: What did you do as a senior engineering fellow?

A: Pretty much the same thing that I did as a manager.

Q: So, you are still working with surgical needles?

A: Yes. Yes.

Q: And how long were you a senior engineering fellow?

A: Just about a year, and then I retired.

Q: So throughout your tenure with Ethicon

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the focus of your activity was on the surgical needle product line?

A: Yes. The primary focus was on that, and I did work on other medical products during that time period.

Q: What other products did you work on?

A: The surgical procedures involving stapling were being developed while I was working in that area.

The staples are made out of wire, and I had expertise in wire and the metallurgical and mechanical metallurgical considerations with that product. And I was very much involved in that.

I was also very much involved in a product that was referred to as a ligaclip, its function was to ligate blood vessels, hence the term ligaclip. And I did quite a bit of work on that.

And also when Johnson & Johnson started with the development of a stent product, I was asked to be the supporting metallurgist in that effort.

Q: What kind of things did you do as the supporting metallurgist?

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A: Made recommendations with regard to materials, recommendations with regard to testing, development of testing techniques, a little bit of assistance in the area of manufacturing.

Q: When you say testing techniques are we talking about these fatigue testing?

A: Yes. Yes.

Q: Any other kind of testing techniques that you were involved with?

A: Along those lines, helping to develop tests that evaluate the crush resistance of the stent, anything that has to do with let's say the mechanical properties of the stent.

Q: When you say crush resistance, what are you referring to?

A: After the stent is expanded, you know, just how much resistance does it have to being collapsed.

Q: And you performed or you, I am just not clear, you developed some testing techniques to determine the crush resistance?

A: I helped with the effort with the engineers who were directly responsible for that

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test, in terms of giving metallurgical input.

Q: So your role was limited to the metallurgical input as you described it?

A: It concentrated on the metallurgical input, yes.

Q: By metallurgical input you mean the behavior of the materials being used?

A: The behavior of the material. But as metallurgical engineers also as part of their curriculum at least at Lehigh, will study some mechanical engineering courses. So we have some basic understandings of mechanical engineering.

Q: And the testing techniques relating to mechanical properties that you have described again would it be fair to say that you provided primarily mechanical input to others who were the ones responsible for those tests?

A: Yes. And in some cases, for example, the evaluating the strength of the tubing that was going to be used for the stent, was initially and for quite some time done in the testing laboratory, that was under my direction at Ethicon.

Q: What percentage of your time at

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Ethicon was spent providing this input that you have described to the stent work?
A: There was about 10 or 15 percent.
Q: And that would be 10 or 15 percent from 1987 until you retired?
A: Yes.
Q: Did you ever design any stents?
A: No.
Q: Would it be fair to say that you have never implanted a stent in a human being?
A: That is very fair to say.
Q: Have you ever observed the deployment of a stent in a human being?
A: Not in a human being, no.
Q: Have you ever reviewed any histological data regarding stents that had been deployed in human beings?
A: Well, I did look at some photographs that were taken of a stent that had been implanted in an artery in a patient, and after that patient had died there was some suctioning done and photographs made and I had looked at them.
Q: When was that?

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A: Well, that would have been in, it was before I retired, but certainly in the '90s. So, 1992, plus or minus a year or so.
Q: Do you recall what stent was involved?
A: No. I do not.
That could have gone back -
Excuse me. That could have been 1989, actually. I am unclear right now as to the exact date.
Q: Was that the only time that you ever had reviewed any histological data of a stent that had been deployed in a human?
A: Yes. That I can recall, sir.
Q: What was the purpose of that review?
A: We were actually working with the FDA to try to determine the best in vivo, I got that wrong, in vitro mode for conducting the fatigue test.
So there were some documents reviewing the testing and reviewing patient experience that were put together that were utilized at a meeting that I attended at the FDA offices in the Washington area.
Q: Do you know how a stent behaves when

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it is implanted inside of a human coronary artery?
A: That is a pretty general question.
I am not so sure that I know how to -
Can you be more specific?
Q: Do you know what it does when it is inside of the body?
MR. GELERNTER: Objection to form. It is vague.
THE REPORTER: Did you answer?
THE WITNESS: No, I didn't.
Q: Do you know how the stent interacts with the tissue inside of the human body?
A: No. That I am sure I don't know.
Q: Do you know what the -
A: And when you say interact I am thinking in terms of you know if you are assuming a biological interaction or whatever, that I certainly, I am not a medical doctor.
Q: Do you know what a stent does to the tissue inside of a human body?
MR. GELERNTER: Objection to form.
A: What it does to it?
Q: Yes.

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MR. GELERNTER: I don't know what you are asking, frankly.
Q: Apart from this one instance where you looked at a histological photograph that you have described to us, have you ever reviewed any other data concerning the performance of a stent inside of the human body?
A: Well, I have seen data for example that talks about the restenosis rate.
You know, I have not really reviewed it because that, I guess as far as I was concerned was dealing with medical aspects of it; but I had seen data.
Q: Mechanically, do you know how a stent performs when it is deployed inside of the human body?
A: Well, mechanically what happens to the stent is that it is expanded, it the stent is expanded by the balloon catheter.
Q: And for what purpose?
A: For the purpose of implanting the stent.
Q: Why do you want to implant the stent?
A: Well, I think the physician wants to

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implant the stent.
Q: So you don't know the purpose for the, for which the stent is implanted in a human body.
A: Well, the stent is –
MR. GELERNTER: Objection. That's not what he said.
Q: I just asked the question. I did not mean to characterize your prior testimony.
A: The physician implants the stent to open an occluded artery and to keep it open.
Q: In order to perform that function of opening the artery and keeping it open, does the stent have to have a certain amount of regidity?
A: Yes.
Q: In order to perform its intended function, does the stent have to have a sufficient length to prevent its migration through the arterial system?
MR. GELERNTER: Objection to form.
What do you mean by sufficient length?
Q: Long enough, the longitudinal dimension.

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A: I don't know that length is a critical dimension in migration.
Q: Just so I understand your answer, are you saying that you don't know the importance or is it your opinion that length is unimportant in the design of the stent?
A: Well, I think your question was is length important in terms of migration.
Q: Yes.
A: And I don't feel that length is important in terms of migration.
Q: Is the ratio of length to expanded diameter important in terms of migration?
A: No. I don't think it is.
Q: How about length to unexpanded diameter, is that important?
A: No. I don't think so.
Q: Do you believe that a stent which is shorter in length than its expanded diameter will avoid migration when it is implanted in a human coronary artery?
A: I think there are probably lots of conditions under which that structure that you described, very generally, would not migrate.

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Q: And what conditions are those?
MR. GELERNTER: Let me note my objection to form to the prior question.
Q: Yes. You said under certain conditions, and I want to know what those conditions are in your view?
A: I think if a stent were sufficiently expanded to press against the arterial wall, that the opposing force of the arterial wall would keep it in place.
Q: Any other conditions that you can think of?
A: Not at this moment.
Q: And is that opinion based upon some test data that you have reviewed?
A: No. It is not.
Q: What's it based on?
A: Well, it is based on a number of factors, some of them being my, I mentioned that I worked on ligaclips. There is perhaps some similarities between ligaclips and stents, of course the difference is the ligaclip is on the outside and the stent is on the inside. Also, just knowing general engineering principles.

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Q: I apologize, I am not really familiar with a ligaclip. Could you describe generally to me what a ligaclip is?
A: Yes. A ligaclip is used for the exact opposite reason of a stent, it is used to ligate or close off a vessel. So, it is placed across the outside of a vessel and it is, they are quite often stainless steel and they are quite short in length relative to the length of the blood vessel and they are put across.
And the mechanical force of the blood vessel squeezing back on the clip, if you will, is sufficient to keep them in place.
As an engineer I look at the stent and kind of the, the similar engineering principles only operating on the inside rather than on the outside.
Q: Is there any blood flow over the ligaclip?
A: No.
Q: You indicate that your conclusion was also based on general engineering principles. Could you explain that, what principles are we talking about?

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A: Well, I understand forces and how they work and how they act upon structures, and I have worked with tubing, I have worked with O-rings, as an engineer, working in that type of field – I have developed a lot of experience over the years.

THE WITNESS: When do you take a break?

MR. BAILEY: Any time that you want to take a break, it is all right.

THE WITNESS: I am all right for now.

Q: The stent related work that you performed at Materials Technology Associates, was all of that work done for Johnson & Johnson or its related companies?

A: Yes.

Q: Apart from your work on this lawsuit have you ever had occasion to conduct any sort of testing or analysis of a non-Johnson & Johnson stent product?

A: Yes, I have.

Q: What were those occasions?

A: I was supplied some stents, and I am not sure who the, who manufactured them sitting

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here.

And I was asked to determine what material they were made of. And I was also given some products that were, the manufacturing process, the way in which they were constructed, involved welding. So, I did a metallurgical analysis of that material to examine it in the weld area.

Q: Do you recall whose stent that was?

A: I think that was, I think it was a stent made by an Israel company, but I am not positive.

Q: Who asked you to do this work?

A: One or another engineer at Cordis.

Q: Did Cordis also ask you to do the work where you were asked to determine the material that the stent was made of?

A: Yes, I did.

Q: Just so I am clear, you are not sure whose stent that was either?

A: Actually, there was a couple of them that I did that on and I am not sure whose they are now.

Q: So, apart from what you have

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just described, these tests where you were asked to determine the material the stent was made of and the test where you were asked to do a metallurgical analysis on welds, did you do any other analysis of non-Johnson & Johnson stents again excluding the work that you have done on this lawsuit?

A: I do not remember any others.

Q: When is the first –

A: Excuse me. I think I looked at one made out of nitinol, and I am not even sure if that was, if that was made for Johnson & Johnson or if it was a competitive so-called competitive product. So yes, there is a metal called nitinol and I looked at one of those.

Q: When is the first time that you recall ever seeing the ACS Multi-Link stent?

A: A few months ago.

Q: How did it come to your attention?

A: Through Patterson Belknap.

Q: Patterson Belknap are Cordis' attorneys in this case?

A: That is correct.

Q: Have you ever seen any studies

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comparing the performance characteristics of the Multi-Link stent with Cordis' so-called Palmaz-Schatz stent?

MR. GELERNTER: What do you mean by performance characteristics?

Q: Just anything about the performance of the device.

MR. GELERNTER: Objection to form.

A: I reviewed some of the ACS materials and I do not remember seeing a comparison in there and I have not, I have not seen any comparison that Cordis might have made.

So, I think the answer to your question is that no I don't think that I have seen a comparative study.

Q: You said you reviewed some ACS materials. Would these be the various brochures that are attached to your declaration?

A: Yes. That is correct.

Q: Apart from those materials that are attached to your declaration have you reviewed any other materials regarding the ACS Multi-Link stent?

A: I think the only thing in addition

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to that, the instructions for use that are in my declaration, I think were the European instructions for use, and I have looked at the U.S. instructions for use.
Q: Anything else?
A: As far as ACS materials?
Q: Yes.
A: No.
Q: Have you looked at any materials prepared by Johnson & Johnson, perhaps -
Let me strike that question.
Have you looked at any materials prepared by Cordis regarding the ACS Multi-Link stent?
A: No. I have not.
Q: Have you looked at any materials prepared by Cordis' attorneys regarding the ACS Multi-Link stent?
A: Comparing that?
Q: No. Just describing it in some fashion.
A: I don't think so. No. Not beyond what's in my declaration.
Q: Are you an inventor or co-inventor on

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any U.S. patents relating to stents?
A: No. I am not.
Q: Are you an inventor or co-inventor on any U.S. patent applications relating to stents?
A: No. I am not.
Q: Prior to your involvement in this lawsuit, have you ever rendered an opinion on infringement of a U.S. patent?
A: No.
MR. GELERNTER: Are you talking about in the context of a lawsuit?
MR. BAILEY: Yes. Excluding his work on this lawsuit.
MR. GELERNTER: But, your question is directed to opinions rendered in a lawsuit as a witness?
MR. BAILEY: No. It was not limited to that, actually. I think his answer was, no, so I mean if -
THE WITNESS: You have managed to confuse me a little bit here. Can you rephrase the question.
MR. GELERNTER: You are not talking about casual conversations, I assume you are

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not.
MR. BAILEY: No. We are excluding those. I will just reask the question.
THE WITNESS: If at some time 20 years ago I exclaimed holy heck that -
MR. GELERNTER: You are not asking about that and I take it you are not asking about privileged communications that he may have had with counsel?
MR. BAILEY: Actually, I am just asking for a yes or no at this point.
I think if he has had privileged communications I would like a yes or no answer to that.
Q: Let me ask the question again just so that we are clear. Prior to your involvement in this lawsuit, have you ever rendered an opinion concerning infringement of a U.S. patent?
MR. GELERNTER: Objection to form. Are you excluding casual conversations?
Q: We will exclude casual conversations. In other words, where you were -
A: I don't think I have.
Q: Fair enough. I think we have gotten

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the answer. Okay. Do you have any formal training in rendering infringement opinions?
A: No. I do not.
Q: Have you ever attended any class or seminar to learn how to render an infringement opinion?
A: No. I have not.
Q: Have you read any cases or court decisions on that subject?
A: No. I have not.
Q: Have you studied any legal treatises on the subject?
A: No. I have not.
Q: For purposes of your work in this lawsuit then, how did you go about learning how to render an infringement opinion?
A: Well, I had assistance from the attorneys at Patterson Belknap.
Q: What did they tell you? I mean, that is too broad of a question.
I will take it one step at a time.
When were you first contacted by the attorneys at Patterson Belknap to render an infringement opinion in this case?

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A: I was first contacted some time around June or July of 1997.
Q: And do you remember the name of the individual who contacted you?
A: Yes. Mike Timmons. Sorry Mike.
Q: Mr. Timmons is with us today.
What did Mr. Timmons tell you that they wanted you to do?
A: Initially, I think what they wanted me to do is just review some documents, and give them some thoughts as to what you know somebody working for the company or not with a huge vested interest might think of different issues and just review technical literature, and give them verbal feedback as to what I thought about different issues.
Q: And did they send you any documents or technical literature to review?
A: They sent or gave, you know, yes, I received technical documents to review.
Q: Did they send you any technical documents apart from the materials that are attached to your declaration?
A: Nothing else that I can recall

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associated with the ACS work.
Q: Now, you said that they asked you to give your thoughts on different technical –
MR. GELERNTER: When you say what's attached to this deposition, I assume you mean what's referenced in his declaration?
MR. BAILEY: Yes. We can fairly include that, I think, yes.
Q: What kind of technical issues did they tell you that they wanted you to give them some thoughts on?
A: Well, asking questions in terms of you know how does the ACS stent – I don't know if work is the right term – but you know look at its characteristics and features, and do I think that it is similar to, infringes upon the patents that are assigned to Johnson & Johnson.
Q: Did they send you any patents to look at?
A: Yes.
Q: When they asked you to determine if it infringed upon any patents of Johnson & Johnson, did you know what that meant?
A: I guess I, initially I had a layman's

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term or a layman's understanding. I guess everybody, engineer who has any patents or has ever seen any, probably has some idea on that subject.
Q: What was your –
I am sorry.
A: But then they went on to define a kind of a legal patent law definition of infringement.
Q: What was your layman's understand?
A: From a layman's understanding, if I have a patent on a glass as an example, and I see something that looks just like what I have described in my patent – do I think there is infringement – yes, I think there is infringement.
Q: So, you are comparing someone else's product with the product that is illustrated or described in your patent?
A: Yes.
Q: And then you said that they, the attorneys for Patterson Belknap went on to define a legal definition of infringement for you and what did they tell you in that regard?

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A: Well, they described that there is two things that you have to do. You have to look at the claims, understand the claims of the patent and then compare the claims made by the other product, the product that you think might infringe and see if all aspects of the product that you think infringes are in fact in the claims of the patent that you viewed.
And you have to look at the language and the specification and the patent prosecution file.
Q: Did they explain to you how you go about acquiring an understanding of the claim language?
A: Yes.
Q: What did they tell you?
A: Well, you have to read the specification and understand what it is that the inventor has used to describe their terminology that they use in the claim language.
Q: Anything else?
A: I think that's it.
Q: Was all this information provided to you in your first conversation with Mr. Timmons?

A: Actually, it was not, no.
Q: Besides telling you that they wanted you to review some technical materials and get your thoughts on technical issues, was anything else discussed in your first conversation with Mr. Timmons?
A: No, not that is recall, no.
Q: Was that a personal meeting or a telephone call?
A: It was a personal meeting.
Q: Where did that occur?
A: In the Patterson Belknap office.
Q: Did Mr. Timmons then give you some materials to take with you to review?
A: No. He did not at that time. I don't think he did.
Q: So you left the meeting with no documents that had been provided to you?
A: That's right.
Q: Did you do anything more on this project before, well, I should say -
I will ask you a preliminary question.
I assume after this first meeting you

had a subsequent contact with attorneys from Patterson Belknap?
A: Yes. That is correct.
Q: Did you do anything on this project between your first meeting with Mr. Timmons and the time that you had the second contact with the Patterson Belknap attorneys?
A: No. I didn't.
Q: When was your second contact with the Patterson Belknap attorneys?
A: I don't remember the exact date, but some time later, perhaps in July or so.
Q: So a matter of a few weeks after the first meeting?
A: Yes, or several weeks.
Q: Was this another personal meeting?
A: I had a telephone conversation and then there was a meeting later on, and I am losing track of the dates exactly when they occurred, but some time thereafter.
Q: Was this telephone conversation with Mr. Timmons?
A: Actually, I think it was with John DiMatteo.

Q: And then the subsequent meeting that you referred to was that in the Patterson Belknap offices?
A: Yes.
Q: Who was present there besides yourself?
A: That was Scott Howard and John DiMatteo and myself.
Q: And Mr. Howard is another one of the Patterson Belknap attorneys?
A: Yes.
Q: What was discussed at the second meeting?
A: I think at that point in time why they, they either gave me some information or said that they would very soon be FedExing me some information for me to review.
Q: Was anything else discussed at that meet something?
A: Well, I think we may have looked at materials, they may have asked me for some thoughts on it. I am not exactly positive if it was at that meeting or then a subsequent meeting after I had a chance to look over data.

Q: Did the Patterson Belknap attorneys provide you at the second meeting with their views on the question of infringement of any Johnson & Johnson patent?
MR. GELERNTER: Objection to form.
You can answer.
Q: You can answer.
A: I think they were asking me if I thought it infringed.
Q: They did not tell you what they thought?
A: No. We - some of these patent attorneys are engineers, too. We may have started drawing pictures and so forth and exchanging ideas. But I think it was primarily a matter of asking me what I thought about it.
Q: Was it at this second meeting when you were provided with what you have explained to us was the legal definition of an infringement analysis that you were given?
A: No. It was not.
Q: All right. So then either at this second meeting or some time thereafter by facsimile you received some materials from the

Patterson Belknap attorneys to review; is that correct?
A: Yes.
Q: Again, this would be about July of 1997?
A: No. Quite a bit of time has gone by now, we are getting into the fall of 1997.
Q: September or October?
A: Yes.
Q: And I take it then that you reviewed the materials that they provided to you.
A: Yes.
Q: How much time did you spend doing that?
A: The initial review?
Q: Yes.
A: About five or ten hours.
Q: Was there then a subsequent contact with the Patterson Belknap attorneys?
A: Well, then we started working on putting the declaration together.
Q: And just logistically how did that happen, was it done by personal meetings or telephone conversations?

A: Yes. Both.
Q: Both. Okay. What was the first step in that regard, did they send you a draft to review?
A: We worked on a draft together.
Q: When you say we worked on it together, explain to me just the mechanics of how the first draft came into existence?
A: I think the attorneys started putting down some documentation on to a piece of paper that you know would be in the proper format if you will, because an engineer I don't know, I did not know how this ought to be put together.
And then we worked together on the wording and the explanations and comparison of the claims in the patent with the ACS materials.
Q: Was this all done sitting around a table, so to speak, at a meeting?
A: Some of it was done sitting around a table, and as we had time to think about things and review it, it was done with fax messages back and forth.
Q: You have described to me now two meetings that you had with the Patterson Belknap

attorneys. Was this drafting of the declaration commenced then at a subsequent meeting?
A: Begun on a separate –
Q: Perhaps the question was not very clear.
You described to me a first meeting that you had with Mr. Timmons, and then a subsequent meeting that you had with Mr. DiMatteo and Mr. Howard. I take it there were still further personal meetings with the Patterson Belknap attorneys?
A: Yes, there were.
Q: Would it have been the third such meeting where the drafting of the declaration was commenced?
MR. GELERNTER: Objection to form.
A: Well, I don't remember exactly.
Q: How many meetings altogether do you recall having with the Patterson Belknap attorneys?
A: Oh, maybe four or five.
My son works in the city, and I like coming in and having lunch with him.
So I would come in and have lunch with

him and say could we get together for an hour – at Patterson Belknap – so that I could enjoy a nice lunch with my son and meet briefly with the lawyers. And at that time I lived in New Jersey, and go back home to New Jersey.
Q: Was there a meeting with the attorneys where you and the attorneys started with a blank piece of paper and began then to draft the declaration?
A: Well, Scott started putting some things together and showed that to me and then we worked from there.
Q: Scott Howard?
A: Yes. Mr. Howard. Excuse me.
Q: The initial document that Mr. Howard put together for you, was it a complete declaration that you were then asked to review?
A: I don't think it was a complete one at that time, no.
Q: Do you remember how long it was, the number of pages?
A: Four or five or six, I am not sure exactly.

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MR. GELERNTER: Some time in the next ten minutes could we take a short break?
MR. BAILEY: Sure. Sure.
Probably now is as good a time as any.
THE VIDEOGRAPHER: The time is 11:02 a.m. and we are going off the record.
(Recess).
THE VIDEOGRAPHER: The time is 11:18 a.m. and we are back on the record.
MR. GELERNTER: Before we begin, I want to put on the record something that I told Mr. Bailey and Mr. Nagy during the break, which is that we all understand that the judge has imposed a limit of 40 hours of deposition questioning by each side in connection with the preliminary injunction motion.
And our calculation of time, based on the times announced by the court reporter in the prior depositions, is that prior to the start of Mr. Kula's deposition yesterday that ACS, I am sorry, yes, that ACS had used 31.9 hours of its time in questioning

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witnesses.
And prior to the start of Mr. Kula's deposition yesterday, accordingly only had 8.1 hours remaining.
I don't want there to be any confusion of that about that. Mr. Nagy has told me that he calculates the time differently, and we are faxing over a document that should show how much time was consumed by ACS questioning in each deposition.
But, I want counsel to understand that when the 40 hours come, the deposition questioning ends.
How much time did I take up saying that?
THE VIDEOGRAPHER: Two or three minutes.
MR. GELERNTER: What time is it now?
THE VIDEOGRAPHER: It is 11:19.
MR. GELERNTER: Okay.
BY MR. BAILEY:
Q: Mr. Bendel, in this series of meetings that you had with the Patterson Belknap attorneys, leading up to the preparation of your

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declaration, did they ever show you or ask you to review any documents other than the ones that are identified in your declaration?
A: None that I can recall.
Q: How much total time did you spend from the time you were first asked to undertake this project until the time you actually signed the declaration?
A: I would say approximately 20 to 30 hours.
Q: Did you conduct any physical testing of products as part of your analysis?
A: No. I did not.
MR. GELERNTER: As part of signing the declaration?
MR. BAILEY: As part of his opinion work in this case.
A: As far as signing that declaration, I did not do any testing prior to signing that declaration.
Q: Have you done any subsequently?
A: I have manipulated an ACS stent by hand and I would describe that as testing of the stent, if you like.

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Q: What kind of manipulation did you do?
A: Bent it.
Q: Was it an expanded or unexpanded stent?
A: It was an unexpanded stent.
Q: Was it mounted on a delivery system?
A: Yes. It was.
Q: What kind of a delivery system?
A: I am not sure that I know that.
Q: Did it have a guide wire as part of it?
A: I am not positive that it did.
Q: Is this something that the Patterson Belknap attorneys asked you to do?
A: They showed me an ACS stent, and I asked to look at it and to manipulate it and examine it.
Q: Why did you want to do that?
A: I wanted to see how the deformation took place, what sort of geometric change occurred when the stent bent.
Q: Did you draw any conclusions from your manipulation?
A: Yes, I did.

Q: What were those?
A: Well, one conclusion was that the connecting member in the ACS stent did bend to some extent.
Q: Is that something that you were able to observe with the naked eye?
A: Not with the naked eye, no.
Q: You were looking at it under a microscope?
A: Not a microscope either, I was looking at it with a magnifying glass.
Q: What power?
A: I believe it was about 5 X. 5 to 10 magnifications.
Q: Did you draw any other conclusions?
A: No. I did not.
Q: When you say the connecting member did bend, how was it bending, could you describe that for me?
A: You could observe the connecting member's orientation; some of the connecting member's orientation within the slot, and you could see that the connecting member, the angular relationship within the slot changed from being

parallel to being non-parallel.
Q: When you say it changed from parallel to non-parallel, with respect to what are you talking about?
A: The longitudinal access.
Q: When it assumed what you called the non-parallel condition, exactly what direction was it heading?
A: In the direction that I bent it, in the direction of the curvature.
Q: And where was the bending that you observed occurring?
A: Some of the bending that I observed occurring was in the connecting link.
Q: So the link itself was bending, you observed that?
A: I observed that there was bending at the base of the connecting member.
Q: At the place where the connecting member joins to rings?
A: In that area, yes.
Q: Did you observe bending anywhere else?
A: There were other geometric changes that occurred around the stent, some of them in

the rings. I don't, you know, I observed other bending taking place. Whether or not take that was contributing to the actual bending of the stent I couldn't tell you.
Q: So, the bending you observed then was in the rings and at the joint between the connecting member and the rings?
A: No. I don't think I said that.
MR. GELERNTER: That's not what he said.
Q: I will reask the question.
Did you see bending in the connecting member?
A: I saw bending in the connecting member, yes.
Q: Where in the connecting member?
A: At the, in the area of the junction of the connecting member with the ring.
Q: And how big of an area are we talking about here, just so that I can pinpoint where this bending you observed occurred?
MR. GELERNTER: Objection to form.
A: I looked at this at low magnification. So, it would be difficulty

with what I did to quantify, give you a quantifiable answer on that.
Q: Perhaps if I could tackle it a different way.
To your knowledge how long are the connecting members in the Multi-Link?
A: I am going to estimate this based on knowing that the stent is 15 millimeters, so the connecting members are in the range of approximately one-and-a-half millimeters.
Q: You have never actually measured the length for purposes of your analysis?
A: That is correct.
Q: Assuming that the length of the connecting members are what you have just described, can you quantify the region of bending that you observed as some percentage of that length?
A: Not with the magnification that I looked at it.
Q: Can you estimate?
A: You know, I just, as an engineer I really don't like to make estimates that are guesses.

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Q: You said you also observed some bending occurring within the rings themselves?
A: I may have misspoken there in that I saw some geometric changes when I looked in the tension side of the stent. I saw that there was some closing of the loops on the tension side, the loops of the rings. I couldn't tell you if that contributed to the actual bending of the stent.
Q: Did you observe any other geometric changes in the rings?
A. No. I did not.
Q: What does the term prosecution history mean to you?
A: I think that is a patent law legal definition of, as a, when a patent is filed I guess somebody keeps a complete record of all of the documentation that goes back and forth between the inventor and the patent office.
And that file then is collected by somebody and describes the, you know, everything that went on with regard to getting the patent.
Q: Did you review the prosecution history of the patents that were the subject of your

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declaration?
A: Yes, I did.
Q: How much time did you spend reviewing them?
A: That was part of that overall review that I talked about.
Q: I know. I am trying to break out the amount of time specifically devoted to the task of reviewing prosecution histories.
A: An hour or so.
Q: Did the contents of the prosecution history play any role in your infringement analysis?
A: Well, yes. They played a role in the infringement analysis in that I did that as part of the infringement analysis.
I don't remember if I included that when you ask me earlier, what I did for the infringement analysis, but that was part of it.
Q: Does the term prior art mean anything to you?
A: Mostly as a lay term.
Q: Tell me your lay definition.
A: Well, I have some patents of my own,

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and I understand that as part of obtaining a patent you have to review the prior art to see what went on before you, to see whether or not what you have would claim as an invention truly is, and that there is not prior art that teaches you how to do what you have claimed to have done with your patent.
Q: Did he review any prior art as part of your infringement analysis in this case?
A: Umh, I reviewed as I said the information that was in the prosecution history. I think there are examples of prior art that are listed in the patent. I did not, I think as part of the patent you list prior art and I did not review those.
Q: Is there any reason why you didn't review them?
A: No.
Q: Your declaration renders an infringement opinion on two different patents; does it not?
A: Yes. That is correct.
Q: And for shorthand purposes can we refer to one patent as the '762 patent?

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A: Please.
Q: And the other patent as the '417?
A: Yes. Please.
Q: Are you aware that the '762 patent is undergoing reexamination in the patent office?
A: Yes, I am.
Q: Were you aware of that at the time that you signed your declaration?
A: I don't think I was, no. I don't know what its status was at that time.
Q: Do you have any understanding of how the claims of the '762 patent can be affected by the outcome of the reexamination?
A: No. I don't.
Q: Do you have any understanding of how the claims of the '417 patent can be affected by the outcome of the reexamination?
A: No. I don't.
Q: Are you aware of the '665 patent?
A: I think I am, yes.
Q: That's a third patent in the name of Dr. Palmaz relating to stents?
A: Yes. Yes.

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Q: Did you look at that patent as part of your infringement analysis?
A: No. I did not.
Q: Did you look at the reexamination proceedings relating to the '665 patent as part of your analysis?
A: No.
MR. BAILEY: Would you mark this as Bendel Exhibit 1, for identification.
(Bendel Exhibit 1, Declaration of Lee P. Bendel, marked for identification as of this date.)
Q: Mr. Bendel, I have handed you a document that we have marked as Exhibit 1; and is this in fact the declaration that you prepared for purposes of this lawsuit?
A: Yes, it is.
Q: Does this declaration fully set forth your opinions concerning infringement of the '762 and '417 patents?
A: It did as of the time that I signed it, yes.
Q: Is there something that you want to add at this point?

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A: We had some discussions about my review of the examination of the ACS stent just a couple of minutes ago, and that certainly plays a role I think in this, in my opinion.
Q: Anything else that you want to add at this point?
A: Not at this moment, no.
Q: Is there anything in Exhibit 1 that you want to change?
MR. GELERNTER: Just to make it clear, I think you already know that we are not going to be asserting '762 patent at the preliminary injunction hearing. So that is not going be a part of Mr. Bendel's anticipated testimony.
MR. BAILEY: I am aware of that.
A: Let me see if I get this right. I don't anticipate any use of the '762 patent. I had used horrible legal terminology there.
Q: Okay. Any other changes to the declaration that you wish to make?
A: No.
Q: Are there any parts of the declaration that you wish to clarify at this time?
A: Not at this time, no.
Q: Counsel indicated that you will be testifying at the preliminary injunction hearing concerning infringement of the '417 patent. You are aware of that, aren't you?
A: Yes, I am.
Q: Are you going to be testifying at that hearing as to any other topics?
A: I believe I am, yes.
Q: What other topics will you be covering?
A: The enablement of the patent and the best mode of the '417 patent.
Q: And just briefly if you can what opinion do you plan to render on the question of enablement?
A: Simply that someone skilled in the art would be able to look at the '417 patent teachings and be able to produce the device described or apparatus described therein.
Q: In connection with that opinion, do you plan to rely on any documents?
A: I may. I have not specifically, you know, thought of any documents along those lines at this moment in time.
Q: So, as you sit here today you can't identify any documents that you are considering relying on for that question?
A: Yes. I just don't know the answer to that.
Q: Do you plan to rely on any physical testing as a part of your opinion on the question of enablement?
A: Sitting here at that time I am not aware that there will be any physical testing.
Q: What then will be the basis for your opinion on enablement?
A: That would be my, my knowledge with regard to engineering and manufacturing capabilities that might exist within someone skilled in the art, and whether or not someone in fact could use the '417 patent teachings to make and use the apparatus described.
Q: Is that based upon what someone skilled in the art would know today?
A: Today or when the patent was first filed.

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Q: What do you plan to testify to regarding the question of best mode?
A: That, as I understand best mode it is a sort of a legal definition, that is, is there something that the inventor knew as a best way of making this, that is not aware, not available to someone skilled in the art. And I would testify that in my opinion that that is not the case.
Q: In connection with the question of best mode, do you intend to rely on any documents?
A: At this moment in time I am relying upon my experience in the industry; and I have not considered whether or not I would provide documents to support that.
Q: Will your testimony on best mode rely on any communications you have had with others?
A: I don't think it would rely upon, no.
Q: Have you had any communications with Dr. Palmaz?
A: When?
Q: Well –
A: About what?
Q: I thought I had I would start

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generally and work down. I assume you have had conversations at some point with Dr. Palmaz?
A: I spoke with Dr. Palmaz, yes.
Q: Have you had any conversations with Dr. Palmaz in connection with your work on this lawsuit?
A: No.
Q: Do you plan to have any such conversations before you testify at the preliminary injunction hearing?
A: I don't plan to at this moment in time.
Q: Have you had any conversations with Dr. Schatz?
A: No. I have never spoken with Dr. Schatz.
Q: Do you plan to speak with him before you testify at the preliminary injunction hearing?
A: At this moment in time I don't plan to.
Q: If I could direct your attention to paragraph number six of your declaration, which is Exhibit 1, looking at the last sentence of

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that paragraph you indicate that you talked to Dr. Nigel Buller, and can you tell me what you and Dr. Buller discussed?
A: Principally the medical aspects of the use of the ACS stent. Is it used in the typical method of inserting a catheter through the femoral artery, et cetera.
Does it go to where Dr. Buller would want it to go? Does it expand?
Just general questions about his experience with the use of the ACS product.
Q: Do you recall what Dr. Buller told you regarding his general experience concerning the use of the ACS product?
A: Only that he used it.
Q: Did Dr. Buller –
Strike that.
MR. GELERNTER: Are you finished with your answer?
THE WITNESS: Yes.
MR. BAILEY: I am sorry. I did not mean to cut you off.
Q: Did you and Dr. Buller discuss the Palmaz-Schatz catheter, excuse me, Palmaz-Schatz

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stent?
A: I don't recall that we did.
Q: I notice that in paragraph 6 of your declaration you do not mention the conversations you had with the Cordis attorneys in connection with the preparation of your declaration. Is there any reason why you did not mention those conversations?
A: No.
Q: Now, in the body of your declaration you focused upon certain specific claims of both the '762 patent and the '417 patent.
For purposes of my questioning today, I will just focus on your statements regarding the '417 patent if I may.
A: Okay.
Q: Can you describe for me the analytical process that you went through to determine whether the Multi-Link infringed the claims of the '417 patent that you talked talk about in the declaration?
A: Sure. I looked at the claims of the '417 patent and tried to construe what the claims of the '417 patent meant.

So to do that I looked at the claims and the words or language that were used in the claims. I reviewed the specification of the patent to see if the language in the claims had a specific meaning or maybe a different meaning than what I might have or what anybody might have in looking at the word, to make sure that I understood the definition of the words that were used in the claim.

I reviewed that prosecution history, and then I took the elements of the claim individually and compared that with the ACS product as it was described. I came to the conclusion that the claims –

Well you asked me to describe the process, so that was the process that I used.

Q: You say that you compared the claims to the ACS product as it was described; are you talking about the descriptions that are contained in the materials that are attached as exhibits to your declaration?

A: Yes.

Q: Apart from what you have just outlined for me, did you do anything else as part of your

analytical process for determining whether the claims were infringed by the ACS Multi-Link?

A: No. Not that I recall. That encompasses a lot there.

Q: Sure. Did you look at all of the claims of the '417 patent and go through this same analytical process for each claim?

A: Yes. I looked at all of the claims.

Q: And I notice that your declaration only mentions selected claims of the '417 patent.

A: Aha.

Q: Did you conclude that the other claims of the '417 patent were not infringed?

A: The –

Yeah, one of the claims of the '417 patent calls for the, when the product is made out of tantalum. The ACS product is reported to be made out of stainless steel.

So in that particular case I certainly concluded that that claim was not infringed.

Q: Is it fair to say though that the specific claims that you identified in your declaration are the only claims of the '417

patent that you found to be infringed?

MR. GELERNTER: Objection to form.

A: At the time that I did this and with the information that I had from the brochures, etc., etc., it appeared to me that those are were the claims that were infringed.

Q: And has that conclusion changed since the time of the declaration?

A: I have not reviewed the ACS product other than what I described earlier with regard to the bending of the connecting member.

So, I have not done a review, so I am not in the position to say that nothing else would be considered to be infringing at this point in time.

Q: For purposes of the testimony that you plan to give at the preliminary injunction hearing, will your testimony on the question of infringement be limited to the specific claims of the '417 patent that you described in your declaration?

MR. GELERNTER: I will stipulate that during the preliminary injunction hearing we will not be asserting infringement of any

'417 claims other than those listed and discussed in Mr. Bendel's declaration.

MR. BAILEY: Thank you.

MR. GELERNTER: Just so it is clear.

We are reserving the right to assert claims at a date subsequent to the preliminary injunction hearing –

We reserve the right to assert claims other than those discussed in Bendel's declaration, subsequent to the preliminary injunction hearing. And we are not conceding that any of the other claims are non-infringed.

BY MR. BAILEY:

Q: Mr. Bendel, did you review any videotapes as part of your infringement analysis?

A: I saw a videotape of the ACS stent being implanted.

Q: Where did you get that tape from?

A: I viewed that at the Patterson Belknap offices.

Q: Do you know who prepared the videotape?

A: I was provided by Dr. Buller.

Q: Is that the only videotape that you looked at?
A: That is correct, yes.
Q: Do you plan to use any videotapes as part of your presentation at the preliminary injunction hearing?
A: No.
Q: Are you currently involved in making any videotapes to use at the preliminary injunction hearing?
A: No. I am not.
MR. BAILEY: Would you mark this as our next exhibit.
(Bendel Exhibit 2, United States Patent, 5,102,417, date Apr. 7, 1992, marked for identification as of this date.)
Q: Mr. Bendel. I have handed you a document that we have marked as Exhibit 2, and I would ask if you can identify it for me?
A: That is an U.S. patent issued to Julio Palmaz, it is patent number 5,102,417.
Q: Is this the '417 patent?
A: Yes, it is.
Q: That is the subject of your opinion?

A: Yes, it is.
Q: Let me direct your attention to Figure 1A of that patent. Do you understand Figure 1A to show what is called a slotted tube graft?
A: Yes.
Q: And that graft is –
A: I think that may be a slotted tube prosthesis.
Q: You prefer a slotted tube prosthesis?
A: I would like to see what the inventor referred to it as.
Q: Sure.
A: He referred to it as an expandable intraluminal vascular graft or an expandable prosthesis.
Q: So, can we refer to it than as a slotted tube prosthesis?
MR. GELERNTER: Objection to form.
A: The inventor referred to it as a slotted, expandable intraluminal vascular graft or expandable prosthesis.
Q: Have you heard the terminology slotted tube prosthesis?
A: Yes.

Q: And is what is depicted in Figure 1A a slotted tube prosthesis?
A: Yes.
Q: And the prosthesis in figure 1A is it not, is composed of a plurality of elongate members indicated by reference number 75 that run from one end of the prosthesis to the other, with bridges indicated by reference number 77 in between; is that correct?
MR. GELERNTER: Objection to form.
Q: Is that what's depicted in figure 1A; that's my question?
A: Can you read that back to me.
Q: Sure. I will just repeat the question. Is the prosthesis of Figure 1A comprised of a plurality of parallel elongate members indicated by reference number 75, that run from one end of the graft to the other, with bridges indicated by reference number 71 in between adjacent elongate members?
MR. GELERNTER: Objection to form.
A: Well, what you have asked me there describes some of the structure of that, but not

all of it.
Q: What did I leave out?
A: The ends, the surface, a number of things that are part of that Figure 1A.
Q: Is the prosthesis of Figure 1A rigid, meaning that it resists bending with respect to the longitudinal access?
MR. GELERNTER: Objection to form.
A: The inventors have referred to that structure as being rigid relative to the tortuous path in the body cavity.
Q: Would you agree with me that the purpose of the invention claimed in the '417 patent is to overcome the problem of delivering a rigid stent of the type shown in Figure 1A into a tortuous artery?
MR. GELERNTER: Objection to form.
A: That is part of the invention, yes.
Q: And the idea of the invention was it not was to join a plurality of these prosthesis together with one or more flexible connector members that enable the device to articulate with respect to the longitudinal access?
A: Well, the inventors describe a

structure that has a connector member between two prosthesis.

And you are referring to a particular form of a prosthesis. There may be other forms of prosthesis that would be included in the patent claim as a sub-state.

Q: But the thrust of the invention was to join a plurality of these prosthesis together with one or more flexible connector members?

A: The thrust is to join plurality of prosthesis together.

Q: With flexible connector members to provide the bending relative to the longitudinal access?

A: No. With connector members to provide flexibility.

Q: Take a look at column 12 of the patent, the material beginning on line 41 and continuing through to line 47.

A: Okay.

Q: Doesn't it say there that the inventor is using flexible connector members in order to enable the prosthesis to flexibly bend or articulate with respect to the longitudinal

access?

MR. GELERNTER: Objection to form. Are you asking him what the specification says there? Are you asking him what's claimed?

MR. BAILEY: Yes.

MR. GELERNTER: You are asking –

Objection to form. I don't know what your question is.

Q: Can you answer the question, Mr. Bendel?

A: I am not sure I understand the question.

Q: Yes. I am asking is, doesn't the patent there describe the use of a flexible connector member in order to enable the prosthesis to flexibly bend or articulate with respect to the longitudinal access?

A: But, it says what it says there.

Q: And it describes the flexible connector member?

A: As seen in Figure 9 because of the disposition of flexible connector members between adjacent tubular members or grafts or

prosthesis. The graft or prosthesis is able to bend or articulate with respect to the longitudinal access, et cetera.

Q: So, what the inventor had in mind was the use of these flexible connector members?

MR. GELERNTER: Objection to form.

A: No, that's –

Q: No.

A: What the inventor had in mind was a connector member that provides flexibility.

Q: I did not mean to interrupt you. What's the difference between a flexible connector member and a connector member that provides flexibility?

A: Well, a connector member, let's say, is a general situation, and a connector member that is flexible is a specific connector member.

Q: And a connector member that provides flexibility, what is that?

A: Something that might in itself not be flexible.

Q: How can a non-flexible connector member provide flexibility?

A: A hinge.

Q: Does the ACS Multi-Link stent have any hinges in it?

A: No.

MR. BAILEY: I see that we are both running out of tape and we are at the lunch hour so we probably should break at this point.

THE VIDEOGRAPHER: The time is 12:05 p.m. and this completes tape number 1 of the videotaped deposition of Mr. Lee P. Bendel.

(Time noted: 12:05 p.m.)

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AFTERNOON SESSION

1:27 p.m.

L E E BENDEL, having been previously sworn, resumed the stand and testified further as follows:

CONTINUED EXAMINATION

BY MR. BAILEY:

THE VIDEOGRAPHER: The time is 1:27 p.m. and in his tape number 2 of the videotaped deposition of Mr. Lee P. Bendel.

Q: Mr. Bendel, this morning you indicated that you planned to testify at the preliminary injunction hearing on the subject of best mode, and I want to come back to that for a moment.

What do you believe was the best mode known to the inventors at the time the '417 patent application was filed?

MR. GELERNTER: Best mode of what?

Q: The best mode of practicing the claimed invention.

MR. GELERNTER: Objection to form.

A: I really don't know what they might have had in mind.

Q: The claims of the '417 patent that

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you believe are infringed, all of those claims require the presence of this connector member that we talked about this morning; do they not?

A: Yes.

Q: So none of those claims would cover a single stand-alone slotted tube stent, would they?

MR. GELERNTER: Objection to form.

A: As I understand the claim it says a plurality and a connector member connecting it.

Q: Just so that we are clear on this. If someone were to make a stent as shown in Figure 1A of the '417 patent would that be covered by any of the claims of the '417 patent you believe are infringed by the Multi-Link?

A: I don't think so. The claims here are for a stent or a prosthesis connected.

Q: A plurality of prosthesis?

A: Yes.

Q: Joined by a connector member?

A: Correct.

Q: The connector member described in the '417 patent achieves flexibility because of the fact that it is disposed in a non-parallel

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relationship with respect to the longitudinal access of the stent; does it not.

MR. GELERNTER: Objection to form.

Are you talking about the connector member that is referenced in the claims?

MR. BAILEY: The connector member that is described in the patent.

MR. GELERNTER: Are you talking about the specification?

MR. BAILEY: Yes.

MR. GELERNTER: The preferred embodiment?

MR. BAILEY: I have no idea what the inventor thinks the preferred embodiment is. The one described in the patent.

MR. GELERNTER: Objection to form.

A: The description of the connector member in the '417 patent does not specifically say that it must be non-parallel.

Q: It doesn't?

A: It says it may not – it may be parallel, non-parallel.

Q: Does the '417 patent describe any connector member that is parallel to the

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longitudinal access of the stent?

A: It generally describes connector members, it then goes on to describe some non-parallel and gives some further descriptions of connector members. But it doesn't say whether the connector member has to be or does not have to be parallel.

Q: My question though is, does it describe any parallel connector members? By parallel I mean parallel to the longitudinal access of the stent.

A: Again, it describes connector members and it says, I think there is one statement in there that says they may be non-parallel. If it says they may be non-parallel, that may very well imply that they can be parallel.

Q: Turning to the Multi-Link stent for a moment.

The Multi-Link stent has a plurality of longitudinal struts, which separate the individual ring sections; does it not?

A: Yes.

Q: And each, excuse me, between each adjacent pair of ring sections there are three of

these longitudinal struts, are there not?
A: That is correct.
Q: And all of those struts are of equal length; correct?
A: They appear to be of equal length, yes.
Q: They are arranged parallel to the longitudinal access of the stent?
A: Yes. They are.
Q: And they are spaced circumferentially 120 degrees apart around the stent, are they not?
A: An individual grouping of three connecting to –
Q: Yes.
A: – connecting two rings, yes.
Q: I believe you testified this morning that you did some bending of the Multi-Link stent with your bare hands and then looked at the device under a microscope, and you saw some bending where the struts connect to the rings.
A: I did not say microscope.
Q: Excuse me. A magnifying glass.
A: Yes.
MR. GELERNTER: He did not say where

the struts connect to a certain area.
A: I did not say –
Q: My question to you is this, given the configuration of the struts in the Multi-Link that you have just agreed to me exists, can you explain to me scientifically how the bending you saw under your magnifying glass occurs?
A: How it occurs?
Q: Yes. Let me be clear on the question. You examined the device under your magnifying glass and believe you saw some bending.
A: Correct.
Q: My question to you is, do you have a scientific explanation for how the device was able to bend at the location where you believe you saw bending?
A: I applied a bending force to it, sufficient to cause some elastic deformation, some bending, and some of that bending clearly occurred in the connector member.
Q: Where was the elastic deformation taking place?
A: Somewhere in the connector member.

Q: Can you explain to me how elastic deformation is taking place when you have three connector members parallel of equal length spaced evenly around the circumference of the stent?
A: Two of them flexed from their parallel configuration to a non-parallel configuration in the direction of bending.
The third one that was on the compressive side appeared to me to have, I will say buckled somewhat, so it bent in an outward sort of pattern. And that is how you were able to, how I was, not how, how I observed what I observed with this device.
Q: How much force did you apply when you bent the stent?
A: I did it by hand and I can't put numbers on that.
Q: If we could quantify it in some fashion, would you agree with me that the stent starts off as a straight longitudinal device?
A: It is essentially straight.
Q: How did you grip the device?
A: I gripped the catheter portion of the device on either end of the stent.

Q: How far apart were your hands when you were gripping the device?
A: Three or four inches.
Q: And then would I be correct to say that you then moved your hands from a horizontal plane downwardly?
A: As you are moving your hands there, yes, that is correct.
Q: At the point at which you believe you saw bending, how close together were your hands?
A: Oh, I don't really know. And in fact what I did was to bring it around so that I could grip now both ends of the catheter with one hand and hold the magnifying glass with the other hand.
Q: So, when you finished applying the force were the, where the two ends of the stent touching each other?
A: Oh, no.
Q: How far apart would you say they were?
A: Half an inch to three-quarters of an inch. And I would like to qualify that by saying that that is my estimate of, my recollection of what I remember and I am an engineer and I like

to be precise.
Q: Do you still have in your possession the device that you bent?
A: No. I do not.
Q: What did you do with it?
A: Patterson Belknap has it.
Q: How many devices did you bend?
A: One.
Q: Did you apply a bending force to the device multiple times or just a single time?
A: I did it a single time and looked at it, put it down, perhaps a few moments later picked it up and did it again and looked at it.
And I probably looked at it during the course of the afternoon, three or four or five times.
Q: You bent it three or four or five times?
A: Yes.
Q: Okay. Before you saw this bending of the connector members?
A: No, I saw the bend of the connector members the first time.
Q: Why did you continue to bend it?

A: To make sure that I, what I saw was correct.
Q: Did the configuration of the device change on subsequent bendings?
A: I don't know if it could or could not.
Q: I mean did it?
A: Did it?
Q: Did you observe it?
A: No. I did not observe it change, no.
Q: All right. Do you have any way of knowing if the amount of bending force that you applied to the stent is comparable to the kind of forces that are encountered when the stent is being deployed inside of a human patient?
A: No. I do not specifically know that.
Q: Do you have any non-specific knowledge of that?
A: Well, the stents are to go through tortuous paths and, and for example in the videotape that I saw, I saw a tortuous path and the amount of bending that I accomplished seemed to be a reasonable approximation of what I saw on the videotape as far as what a tortuous path

looks like.
Q: What you saw on the videotape, was that a magnified view of the arteries?
A: I don't know if it was or not. It was certainly not anything, it was not 10 X or 100 X type of thing.
I don't know if it was 1.1 X or .9 X or whatever.
Q: Do you remember the name or the title of the videotape that you observed?
A: No. I do not.
Q: You have described that one of the three struts that you observed buckled somewhat.
A: That's what it appeared to me. The bending, the sample as I did was very difficult to examine it, you know holding it in one hand and holding the magnifying glass with the other, so it was very difficult to see totally what was going on.
Q: Where did it buckle?
A: In the connector member.
Q: Where in the connector member did it buckle?
A: I can't say precisely.

Q: And just so I understand when you say buckled, what do you mean by that?
A: It seemed to bend out of the plane that it was in, it is in that annular ring.
Q: Would it be fair to say that it assumed a V-like configuration, is that what you are trying to describe?
A: It was non-straight, whether you want to call it V-like or U-like, or something like that, but it was not straight.
Q: I guess what I am trying to distinguish is, was it curved or was there actually a point with a sharp bend in it?
A: Again, I was not looking at a high enough magnification to make a determination and the other difficulty was that it was difficult to be looking inside.
It was easy to look at what we will call the cross-section of the bend, but it was very, very difficult to be able to look at the compression side of the bend.
Q: The two struts that you said assumed a non-parallel configuration, did it appear to you that the length of those struts had changed?

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A: It did not appear that the length changed.
Q: Did you apply any compressive force to the stent when you were doing this manipulation of the device?
A: Certainly not intentionally. The last question – did I apply a compressive force?
Q: A compressive force to the stent.
A: When you bend something you put the outer fibers in tension and the inner fibers in compression.
Q: Okay. In that sense there –
A: In that sense, yes.
Q: Okay. If we could refer to your declaration, which we have marked as Exhibit 1, and if you could turn to page 9, please.
A: All right.
Q: Under the heading of Claim 1, you have reproduced some of the language from Claim 1 of the '417 patent, and then you have a paragraph of description below that. And in both the language of Claim 1 and in the description which follows, the word prosthesis appears.

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A: Aha.
Q: Am I correct that a prosthesis in the context of the '417 patent means an implantable device that provides some support to a body passage way?
A: It is an implantable device that, yes, I think that –
Q: The second sentence in the body of the text there reads: Each of those –
I should probably read the first two sentences.
You say: The ACS Multi-Link stent has 12 ring sections. Each of those sections is a prosthesis which, when placed in a body passageway and expanded, maintains the opening of the body passageway.
My question is, at the time that you signed the declaration what was your, the basis for your statement that each of the ring sections was a prosthesis?
A: In my opinion in looking at the geometry of that stent as it was described in the ACS literature, it was my opinion that each one of those rings could in fact operate

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independently and be used to act as a prosthesis.
Q: Now, when you say operate independently, operate independently in what sense?
A: Independently of the one next to it, and the one next to it and the one next to it.
Q: Was there any other basis that you had for the statement that each ring section was a prosthesis?
A: The –
No. I think that covers it.
Q: Did you do any kind of physical testing to support your conclusion?
A: No. I did not.
Q: Do you know if the individual rings of the Multi-Link have enough radial strength to hold open a lumen?
MR. GELERNTER: Objection to form.
A: Do I know that?
Q: Yes.
A: It is my opinion that they would have enough radial strength to hold open a lumen.
Q: What's that opinion based on?

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A: General knowledge of engineering, some familiarity with anatomy through my years of working with it. I mentioned previously my work with ligating clips.
Q: I am sorry.
A: The sum total of my experience in the field.
Q: Is it based on any testing of the Multi-Link in a lumen?
A: No. It is not.
Q: Do you know if the individual rings of the Multi-Link have enough radial strength to tack up a flap within an artery?
A: No. I do not know.
Q: Do you know if the individual rings of the Multi-Link have enough length to prevent migration?
A: I think I said earlier that I don't think migration is necessarily a function of length.
Q: Still looking at that same paragraph of your declaration, you make reference to the ACS '995 (SIC) '955 patent, in line 3; do you see that?

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A: Yes.
Q: Was your opinion of infringement based on the stent that is illustrated and described in the ACS '995 patent?
A: Well my opinion was based on the sum total of the information that I looked at, and that was part of it.
Q: Why did you refer to the ACS 99', the '955 patent -
I may have misspoke earlier. I said '995, I meant -
A: You said it wrong, and I heard it right so we were okay on this.
Q: I appreciate that. I think we have lost the question so let me just rephrase here.
Looking at that same sentence you make reference to 35 USC Section 287 (a). What's that?
A: That is where Patterson Belknap helped me out in terms of recognizing some of the legal terminology that must be applied.
Q: Do you know what that section -
A: I don't know what Section 35 USC

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says.
Q: Was it your understanding in conducting your infringement analysis that the ACS '955 patent contained a description of the Multi-Links stent?
A: Oh, yes.
Q: Was the '955 patent one of the documents that you were given to review by the Patterson Belknap attorneys?
A: Yes.
Q: Moving down in your declaration to the next claim element that you discussed, the one that reads quote, disposing at least one connector member between adjacent prosthesis to flexibly connect adjacent prosthesis to each other; do you see that?
A: Yes.
Q: At the time that you executed this declaration it was your opinion that the ACS Multi-Link had such a connector member; correct?
A: Yes. At least one.
Q: At the time that you signed the declaration what was the basis for that conclusion?

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A: Looking at the various documents that are included as exhibits in my declaration.
Q: Are you now making reference to Exhibits D and E that are referenced in this paragraph of the declaration? And I believe the exhibits are attached to the declaration if you wish refer back to them.
MR. GELERNTER: You don't have a copy with exhibit tabs?
MR. BAILEY: I do not, unfortunately.
MR. GELERNTER: I think the exhibit tabs did not xerox either or somebody took them out when they xeroxed this.
Q: I may be able to help you out a little bit, Mr. Bendel. I think Exhibit D was a brochure, I think you have the page open to it right now.
And in reviewing your declaration and this exhibit, does this refresh your recollection that this was Exhibit D?
A: Yes.
Q: And then of course Exhibit E is the next one in sequence, which I think has three - that one, that page right there that you have.

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A: This is D and this is E?
Q: That is E. Yes.
A: All right.
Q: Now in your declaration you quote some language from both Exhibit D and Exhibit E; do you see that?
A: Where are we now?
Q: I am at the bottom of page 9 of the declaration.
A: Okay.
Q: Is this quoted language from Exhibit D and Exhibit E the evidence that you relied upon at the time you signed the declaration to support your opinion that the ACS Multi-Link had the claimed connector member?
A: Yes.
Q: Now, I am going to read what you have quoted from Exhibit D, and you quoted quote, composed of multiple rings connected to multiple links, a unique design that offers an exceptionally powerful combination of flexibility end quote.
Do you see that?
A: Yes.

Q: Where in that quoted language does it say that the links in the ACS Multi-Link flexibly connect the rings?

A: It says that the multiple rings connected to the multiple links offer an exceptional combination of something else and flexibility.

So it is saying that that combination per the ACS literature provides flexibility.

Q: Did the combination of the rings and the links provide the flexibility?

A: That's what they say.

Q: Going down to the language you quote from Exhibit E, quote, 12 rings are linked by 33 articulations for flexibility. end quote.

And again, wouldn't it be true that this language says that it is the combination of the rings and the articulations that provide the flexibility?

A: I am not so sure that it says that.

MR. GELERNTER: It says what it says. Objection. It speaks for itself.

Q: Okay. Do you believe that this quoted language says that the links provide a flexible

connection?

A: It says that the 33 articulations are there for flexibility.

Q: You read part of the sentence; right?

A: I quoted the –

MR. GELERNTER: He answered your question.

Q: It says 12 rings are connected by 33 articulations for flexibility.

A: Aha.

Q: If I could turn now to page 12 of your declaration, and I am looking at the discussion here of Claim 9 that begins in the middle of the page; do you see that?

A: Yes.

Q: There is a reference in Claim 9 to a tubular member; do you see that?

A: Saying Claim 9. The method of claim 1, wherein a thin-walled, tubular member is utilized as each prosthesis; is that what you are referring to?

Q: Yes. A tubular member is a specific shape or configuration of a prosthesis; is it not?

A: Yes. As defined by the inventors.

MR. GELERNTER: Objection to form.

Q: Would you agree with me that a tubular member needs to have the shape of a tube?

A: I am not so sure that I understand that at all.

Q: You don't understand my question or –

A: I don't understand your question.

Q: Okay. Does a tubular member have to be shaped like a tube?

A: Well, in the case of the '417 patent the inventors describe what a tubular member should look like.

Q: And you are referring to the description that is contained in the patent specification?

A: Correct.

Q: Looking down in the paragraph that follows the quotation of Claim 9, you say that the, from the information I have reviewed it appears that the ACS Multi-Link stent is manufactured by taking a thin-walled steel tube and using chemical etching to form the stent pattern; do you see that?

A: Yes.

Q: What led you to the conclusion that chemical etching was used?

A: The information that is contained in their patent, the '955 patent describes a method of manufacture.

Q: Does the use of chemical etching in your view have any effect on the properties of the finished stent?

A: In my view it does not. You asked that, does chemical etching as used to manufacture this slots in the stent or whatever.

Q: Perhaps my question wasn't clear. I meant chemical etching as opposed to some other methodology for forming the stent pattern.

A: Let's start over and ask –

Q: Let me, I will go back and ask the question.

Does the use of chemical etching as opposed to some other technique for forming the stent pattern have any effect upon the properties of the finished stent?

MR. GELERNTER: Objection to form.
What technique, what other technique?
Q: Well, any other technique.
A: You are saying any other technique.
If beating it with a sledge hammer.
We are talking about a technique that
that is suitable for that?
Q: We will limit it to a technique that
is suitable.
A: Thank you counselor, the answer.
Q: All right.
A: I believe the question is, would that
technique as described in '955 be comparable to
other suitable techniques, and my answer is yes,
I think it would be.
Q: Why did you point out in your
declaration the fact that you believe chemical
etching was being used?
A: I just said that because that is what
was provided in the information in the patent.
Q: What I am trying to find out though
is, did that fact have some relevance in your
infringement analysis?
A: No.

Q: Turn to page 13 of your declaration.
And at the top of the page and in the
following paragraph you have used the word slot
or the plural slots, that appears in the claims
of the '417 patent. And my question is, what
does the word slot mean to you in the context of
the '417 patent claims?
A: An elongated opening.
Q: Can a slot be a rectangular opening?
A: Sure.
Q: Where did you get the notion that a
slot is an elongated opening; what's your basis?
A: From the definition of the term in the
'417.
Q: Could you show me what you relied upon
in the '417 patent as the definition?
There is a separately marked copy if
that would be more convenient to use, Exhibit 2.
A: There is, actually I think you read it
earlier. An example of the discussion of what a
slot is, is in column 7.
Q: Which line are you referring to?
A: Line 25. As seen in FIG. 1A, the
slots 82 are preferably uniformly and

circumferentially spaced from adjacent slots.
MR. GELERNTER: You started at line 25
I believe.
A: As seen in FIG. 1A, the slots 82
are preferably uniformly and circumferentially
spaced from adjacent slots 82, as by connecting
members 77, which connect member 77 preferably
have a length equal to the width of slots 82, as
seen in –
No, that's not really where I want to
be.
Let's go down to 44.
Thus, connecting members 77, which are
disposed at the first and second ends of each
slot 82, and between elongate members 75, will in
turn be disposed intermediate the first and
second ends of adjacent slots.
So, it is connecting member 77 and
elongate member 75, which are defining a complete
slot. And further down I believe it talks about
half slots.
Q: Where are you referring to now?
A: Down at 53.
Q: And these two passages you referred me

to are what you are relying upon for the notion
that a slot is an elongated opening?
A: Well, the entire text of here and you
know if I have not picked out all of the exact
portions that clearly define it, that is, because
I have taken enough time to find a portion here
that does define it and there may be others in
here also.
Q: The portions that you referred to are
all descriptions of the embodiment shown in
Figure 1A of the patent; are they not?
A: Yes.
Q: So you have defined the word slot
haven't you to mean the specific example given in
Figure 1A of the patent?
MR. GELERNTER: Objection to form.
A: That is an example of a slot. That
is, that is not specifically the one shown in –
Q: Have you defined the word slot to mean
the example shown in Figure 1A?
A: The example –
MR. GELERNTER: Objection.
A: Example is, shown in 1A is included in
the definition, but it is not limited to that.

Q: Okay. So, I am not clear then. What do you rely upon for your definition of the word slot?

A: I am not so sure that I that I understand the question.

Q: You just pointed out to us two paragraphs or two sentences from paragraph, excuse me, two sentences from column 7 of the patent.

But I thought, and perhaps I misunderstood you, but I thought that those two sentences were the basis for defining a slot to mean an elongated opening; am I mistaken or is that correct?

A: Well, those statements define a slot, they define an elongated opening.

I believe the inventors also talk about the fact that the, and this elongated opening is a rectangle. They talk about other elongated openings that are not necessarily perfectly rectangular in shape. Other shapes can in fact be slots.

Q: Is there any limitation on the shape other than the fact that it be elongated?

A: No.

Q: Is there any limitation on the minimum width of the opening?

A: The minimum - let's see - It shall be as wide as the connecting member 77.

Q: That is in the particular example shown in Figure 1A?

A: Yes.

Q: But in the context of the claimed invention, does a slot have to have a certain minimum width?

A: No.

Q: At the back of your declaration included in the exhibits is a page of drawings with the heading. I will show you the page so that you will see what I am talking about, it is this one.

A: All right.

Q: Entitled infringement of the '417 patent by the ACS Multi-Link stent.

That is one of the exhibits to your declaration; do you see that page.

A: Yes. I do.

Q: Who prepared the drawings that we see on this page?

A: The actual drawing was prepared by Patterson Belknap. I did some sketching to indicate some aspects of what it should look like and they did the actual drawing.

Q: And the sketching that you did are these lead lines that we see on the page?

A: No. No. Some initial sketching to show how to lay it out.

Q: I see. Did you compare the drawing that Patterson Belknap did with the actual ACS Multi-Link stent to confirm the accuracy of the drawing?

A: I compared the, these drawings with the literature that is provided as exhibits in here to see if it was a reasonable facsimile of it; yes.

Q: Would that include the ACS 955 patent?

MR. GELERNTER: Actually, just so record is clear, it is my understanding that these drawings, the graphic description of the stent comes from ACS' own literature.

MR. BAILEY: I am just going with what the witness is telling me.

A: Figure 5 in the 955 patent for example is fairly similar to the figure at the lower portion of that page that we have referred to that is entitled infringement of the '417 patent -

Q: Have you ever -

A: By the ACS Multi-Link stent.

Q: Have you ever seen the ACS Multi-Link stent in its expanded condition?

A: No. I have not.

Q: So, you have no way of knowing if the drawing at the bottom of this page of drawings that we are referring to is accurate or not; do you?

MR. GELERNTER: Objection to form.

A: These copies here are horrible. I thought one of them, one of the photographs provided by ACS did show at least schematically what the expanded extent might look like.

Q: Is that attached to your declaration any place?

A: The ACS literature that I relied

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upon is all attached, but what I am saying is that I can't tell from these photographs, these photographs are so unclear, that I can't say that we in sketching this that I would have specifically looked at that drawing and said okay this is what it is going to look like when it is expanded.

Q. Okay. In your declaration I believe you referred to reference number E which appears on the top drawing, as being the indication of where you found slots in the ACS Multi-Link; is that correct?

A: Aha.

MR. GELERNTER: Well -

A: No. No, wait, that is a quick answer.

Q: Please check.

A: What page of the declaration do you have me in?

Q: I think one place where we can find it, would be if you look at the next page of the declaration that contains a flame chart. I am sorry. We are in different places in the declaration.

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MR. GELERNTER: Yes.

Q: If you find the page of figures that we have been discussing, and now turn the page is there a claim chart?

A: Forward or backward?

Q: Yours must be organized a little bit differently than mine.

MR. GELERNTER: Would you direct us to the penultimate page which the -

MR. BAILEY: Apparently yours and mine are in different order, so let me -

All right.

Q: Page 7, which is the page that precedes the page of drawings that we have just discussed. If you could look at that and see if that refreshes your recollection that reference E is a reference to what you believe to be the slots in the ACS Multi-Link.

A: Yes.

Q: It is?

A: Yes.

Q: It is unclear to me from these lead lines that you have drawn in the figure, exactly where you believe the slots to be.

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I would like to ask you to take this yellow marker, and if somewhere in the middle of the stent could you highlight in and color in what you believe to be one slot in the ACS Multi-Link.

A: All right.

(Witness complying with request).

Q: If I could just borrow that for a moment and see what you have done.

Now, I noticed that in the coloration that you have applied to the drawings, you have colored up to a physical boundary on three sides of the space but you have arbitrarily stopped coloring at the fourth side of this space.

MR. GELERNTER: Objection to the arbitrarily.

Why don't you leave out the adjective and ask the same question.

Q: On the for side of the space you stopped drawing at a location where there was no physical boundary; is that correct?

A: That is correct.

Q: And the same opening that you have colored in also continues, doesn't it, laterally

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of the region that you have colored in?

A: I don't know what you mean by -

MR. GELERNTER: Objection to the same opening?

A: I don't know what you mean by laterally.

Q: In other words, at the location where you stopped drawing at which there is no physical boundary which is this point right here; correct? It is very small, so I apologize.

A: Okay.

Q: That point right there. Okay.

A: Okay.

Q: The opening in the stent actually continues laterally for perhaps, perhaps circumferentially would be a more accurate term, from the area that you have colored in; does it not?

MR. GELERNTER: Objection.

A: The opening?

Q: The opening in the stent actually extends circumferentially from the region that you have colored in?

A: There is lots and lots of open area in

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the stent. You asked me to draw what I thought was a slot in here, and that's what I did.
Q: Okay. Isn't it true that by stopping your coloration at a point where there is no physical boundary, you are able to make the region you color any size or shape that you choose to make it; isn't that true?
MR. GELERNTER: Objection to form.
Q: Do you understand the question?
A: I drew this, I drew within the lines.
Q: But you agree with me –
MR. GELERNTER: Let him answer the question.
Q: I am sorry. I did not mean to interrupt your answer. Go ahead.
A: And I stopped at a point which is at the bottom, if you will, of that row of slots.
Q: But you have agreed with me that at that bottom point there is no physical boundary there?
A: In that there is no, I agree that there is no piece of metal there.
Q: And there is no other kind of a physical boundary there; is there?

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MR. GELERNTER: Objection to form.
A: If I draw a line across there, if I make a plane across there, then I do have a boundary.
Q: I meant a physical boundary in the device as it is actually made and sold by ACS.
A: Well, no, I think there is a physical boundary there.
Q: At that point?
MR. GELERNTER: Objection to form.
A: Not a physical –
Go ahead. You were starting to give an answer.
A: When I fill this glass up there is no physical boundary right now across the glass but when it is full up, it is full.
And I know when the glass ends. So I know where the slot ends.
Q: But, you would agree that there is no physical boundary at that location?
A: Just like there is no physical boundary in the sense that there is no piece of glass on top of my glass here. Yes.
Q: Wouldn't you agree with me, however,

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that if you color in a portion of a space and you stop coloring short of the physical boundaries of that space, you can make the region you choose to color any size or shape you want it to be; can't you?
MR. GELERNTER: Could I have that read back.
(Record read.)
MR. GELERNTER: Objection to form.
THE WITNESS: I am going to answer –
MR. GELERNTER: It is argumentative.
A: I am going to answer it the same way that I said the glass. The glass holds 10 ounces of water, if I pour a gallon of water in there, it is still only going to hold 10 ounces of water, the rest will spill on the floor.
MR. GELERNTER: Some time in the next ten minutes, could we take a short break?
MR. BAILEY: Yes.
Q: If I could pursue your glass of water analogy for a moment.
If you choose to fill up the glass all the way to the top, you will have what a column of water say six or seven inches tall?

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A: Yes.
Q: Okay. But if you chooses to fill the glass only halfway, now you will have a column of water say three inches tall; right?
A: Yes.
Q: If you choose to fill the glass only a little bit, you can have a column of water that is a millimeter tall?
A: Right.
Q: And that is what I was trying to get you to agree with me, that the size and shape of the space you color in can be chosen arbitrarily if you choose not to stop at a physical boundary?
MR. GELERNTER: You know where we started with all this, you asked him to color in a slot.
And now you are asking him if he colored in less than he colored in could he have done that.
Is that what you are asking?
Because frankly, you started all this, by asking him to color in the slot. Now you are asking him if he had done something else, would that be different?

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I don't know what your question is any more, to tell you the truth.
Q: Let me try it a different way.
If you chose to color in the opening in the ACS Multi-Link and you colored all the way to the physical boundaries of that opening, it would be different than the region you have colored in; correct?
A: You asked me to color in a slot.
Okay.
Q: Okay.
A: If you had asked me to color in this water glass, I would have colored it in up to here. I wouldn't have stopped halfway, I wouldn't have stopped one millimeter, I would have colored it in to what is the top.
What constitutes the top is this plane across here. That is what I did here to the best of my ability with a very broad brushed, broad tipped marking pin.
Q: I will allow you that leeway.
A: Thank you.
MR. BAILEY: All right. If we could move on to page 15 of your declaration.

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In the section where you are discussing claim seventeen, do you see that?
MR. GELERNTER: Could I just catch up to you his please?
A: In 15 I see reference to 20.
Q: Page 15.
A: It is paragraph.
MR. GELERNTER: Paragraph. I am sorry. I looked at the paragraph.
Q: Claim 17.
A: All these numbers are starting to blur for me now.
Q: Are you with me now?
A: Yes.
Q: Looking at the second element of claim 17 that you describe on that page, where you see the use of the word grafts; are you me?
A: Yes.
Q: In the context of the '417 patent claims is a graft synonymous with a prosthesis?
A: Synonymous?
Q: Yes.
A: No.

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Q: What's the difference in the context of these claims?
A: Well, intraluminal graphs can be prosthesis; so can other things.
Q: Do you view the word graft to be a narrower term than the word prosthesis?
A: The inventors described or defined an intraluminal graft, and they did define it more narrowly than a prosthesis.
Q: Turn now to page 18 of the declaration.
MR. BAILEY: Actually, counsel asked for a break and we are at a convenient break point, now so why don't we do that.
THE VIDEOGRAPHER: The time 2:25 p.m. and we are going off the record.
(Recess).
THE VIDEOGRAPHER: The time is 2:39 p.m. and we are back on the record.
BY MR. BAILEY:
Q: Mr. Bendel, could you turn to page 18 of your declaration.
A: All right.
Q: And I would like to direct your

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attention to the discussion of claim 25, which appears there.
A: Aha.
Q: And the third element of claim 25 that you discussed, the claim language is and I quote, the wall surface having a substantially uniform thickness. End quote. Do you see that?
A: Yes.
Q: Would you agree with me that a surface is a two dimensional area?
A: I think in the ordinary sense yes. But in the way in which it was defined in the specification of the '417 patent, I think they were referring to that wall surface as actually that angular ring.
Q: Could you show me where in the '417 patent specification you believe that definition appears?
A: I apologize for taking so long. I am missing it.
Here it is. Our wall surface 74 deposed between the first and second ends, 6, 58.
Q: Column six, line 58.

A: Yes.
MR. GELERNTER: Take your time and review the whole thing if you want to. If you are asked to find stuff, take your time and read the report.
A: 658 refers to the wall surface and then on 8 line 6, it says but also because the thickness of the wall surface 74.
Q: Mr Bendel, your infringement opinion regarding the '417 patent covers a number of claims, it covers claims 1 through 3, 9, 11 through 13, 17 –
Let me get my list right.
22, 25 and 29, does it not? You may want to refer to page 2 of your declaration to confirm that.
A: Yes.
Q: Now –
MR. GELERNTER: Do you remember what he said?
A: If you said 1 to 3, 9, 11 to 13, 17, 22, 25, and 29 the answer is, yes.
Q: To the extent that the term graft appears in any of those claims, does it have the

same meaning in each of the claims?
A: I would like to review each one of those claims and make sure –
Q: Certainly.
MR. GELERNTER: It may speed things up if you told him which of the claims has the word graft in it.
THE WITNESS: Right now that is what I am doing now, the scan.
MR. GELERNTER: Not everyone uses that term.
A: I don't see that term in a quick scan of one, I don't see it in two, and I don't see it in three.
Q: Perhaps –
MR. GELERNTER: The first time I see it is 17.
Q: I don't want to interrupt you, but I want to make sure my question is clear. I am not asking you to agree that the graft appears in every claim, because it doesn't?
My question is, each time that the word does appear in those claims, does it have the same meaning?

A: I want to see the term graft in the claim, so that I can answer and give you an answer that I am comfortable with.
So, we are saying that 17 has the term graft in it?
MR. GELERNTER: That's right.
Q: Yes. And 22. 25?
A: Yes. 22. 25.
Q: 25.
A: 25.
MR. GELERNTER: 25 I think does not.
Q: Correct.
MR. GELERNTER: 17.
Q: 17, 22 and 25.
A: I guess I think it means the same thing.
Q: Every time that the word prosthesis appears in the group of claims that you have analyzed, does it have the same meaning in each claim? And perhaps to assist you claim 1, 2, 3, 9, and 29.
A: Yes. I think it does.
Q: Okay.
MR. BAILEY: I believe that is all of

the questions that I have for Mr. Bendel at this time.
Before I turn it over though, I would like to just state for the record, following up on your concern regarding the amount of elapsed time for depositions that had been used.
It does appear that there is some difference of opinion between the two sides about the amount of elapsed time, and you did offer to provide us with your list, and if you could fax that over today or tomorrow, we will compare it.
MR. GELERNTER: The back-up that I had was not consistent with what I thought when I spoke earlier.
And in fact you have more time than I thought. The number that I have, and again I would have to double check it to know that it is accurate, is 26.1 before the Kula deposition yesterday, which was 153 minutes. So before the Kula deposition you had 26.1 hours remaining.
MR. BAILEY: If you could fax us your

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list by, upon deposition by deposition break, then we could resolve the matter.

MR. GELERNTER: Thank you. I have no questions.

THE VIDEOGRAPHER: The time is 2:51 p.m., January 22, 1998, and this completes the videotaped deposition of Mr. Lee P Bendel, and this completes tape number 2.

(Time noted: 2:52 p.m.)

LEE BENDEL

Subscribed and sworn to before me this day of 1998.

CERTIFICATE

STATE OF NEW YORK)
) ss.
COUNTY OF NEW YORK)

I, ROBERT X. SHAW, CSR, a Notary Public within and for the State of New York, do hereby certify:

That LEE BENDEL, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 23rd day of January, 1998.

ROBERT X. SHAW, CSR

Lawyer's Notes

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Lawyer's Notes

E X H I B I T S

marked at the

deposition of

LEE P. BENDEL

on

JANUARY 22, 1998

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT CORPORATION, Defendants.	CASE NO. 97-550 **DECLARATION OF LEE P. BENDEL**

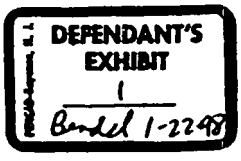
DECLARATION OF LEE P. BENDEL

LEE P. BENDEL, being duly sworn, deposes and says:

1. I am a metallurgist by training and experience. I hold a B.S. and a M.S. in Metallurgical Engineering from Lehigh University. I have spent the past 25 years in the field of metallurgy, principally involving research, testing and development of medical instruments and devices. I submit this declaration in support of plaintiff's motion for a preliminary injunction because, in my opinion, the defendants' Multi-Link stent infringes two patents licensed to plaintiff.

A. **Credentials**

2. Following my graduation, I worked in various metallurgical capacities at Carpenter Technology Corporation. From 1969 until 1994, I worked as a metallurgical engineer for Ethicon Corporation. Beginning in 1987, I worked on various balloon



expandable stent projects, including projects relating to the Palmaz stent and the Palmaz-Schatz stent. Those projects included a review of the fatigue properties of 316L stainless steel, the development of a test to evaluate the fatigue life of stents, and the development of an inspection method using a scanning electron microscope to evaluate stent expansion and fatigue life.

3. Currently, I am the Vice President of Material Technology Associates Inc., an engineering consulting firm. In this position I continue to work on stent-related projects, including an analysis of a variety of stent manufacturing processes including tubing supply, a laser slot cutting process, and an electropolishing process. I have also worked on a method to evaluate fatigue erosion *in vitro*, inspected expanded and fatigue tested stent designs, evaluated alternate stent materials and manufacturing processes, and evaluated stents manufactured by various companies.

4. I copy of my curriculum vitae is attached as Exhibit A.

B. Infringement Analysis

5. I understand that, for the purposes of plaintiff's motion for a preliminary injunction, Cordis Corporation ("Cordis"), is asserting that Advanced Cardiovascular Systems, Inc. and Guidant Corporation (collectively "ACS") infringe claims 23 and 34 of United States Patent No. 4,739,762 ("the '762 patent"; Exhibit B) and infringe claims 1-3, 9, 11-13, 17, 22, 25, and 29 of United States Patent No. 5,102,417 ("the '417 patent", Exhibit C) by making, using, selling, and/or offering for sale the Multi-Link stent.

6. I have reviewed both the '762 patent and the '417 patent and their related file histories. I have also examined the ACS Multi-Link stent and brochures describing the Multi-Link stent (Exhibits D, E and F), the users' guide which accompanies the Multi-Link stent (Exhibit G), ACS patents, such as United States Patent No. 5,421,955 ("the '955 patent"; Exhibit H), which is marked on the Multi-Link stent users' guide according to 35 U.S.C. § 287(a), a Guidant web page entitled "Stent Implantation Procedure" (Exhibit I), and Guidant's October 2, 1997, press release (Exhibit J). I have also talked to Dr. Nigel Buller, an English cardiologist who has actual clinical experience in using the ACS Multi-Link stent.

7. It is my opinion that ACS Multi-Link stent has all of the elements of claims 23 and 34 of the '762 patent and claims 25 and 29 of the '417 patent.

8. It is also my opinion that a combination of ACS manufacturing the Multi-Link stent and a doctor using the stent as suggested in the ACS users' guide which accompanies the Multi-Link stent practices all of the elements of claims 1-3, 9, 11-13, 17, and 22 of the '417 patent. The ACS Multi-Link literature makes it clear that the purpose of the stent is for a physician to implant the stent into a body passageway to expand the opening of that body passageway with the stent. The following is a summary of my infringement analysis

THE ACS MULTI-LINK STENT INFRINGES CLAIMS 23 AND 34 OF THE '762 PATENT

9. I understand that Cordis is not asserting either claim 13 or claim 24 of the '762 patent in its Motion for a Preliminary Injunction. However, because claims 23 and 34 depend from claims 13 and 24, respectively, I have analyzed claims 13 and 24 to determine if the ACS Multi-Link stent contains all of the elements of those claims.

10. As shown in Exhibit K and as described below, the ACS Multi-Link stent contains all of the elements of claim 13 of the '762 patent.

Claim 13 An expandable intraluminal vascular graft, comprising

The ACS Multi-Link stent is an "intraluminal vascular graft" as defined in the '762 patent. As explained in the users' guide, the ACS Multi-Link stent can be expanded by a balloon. (Exh. G).

a thin-walled tubular member having first and second ends

The ACS Multi-Link stent is a thin-walled tubular member that has two ends. From the information at my disposal, it appears that the ACS Multi-Link stent is manufactured by taking a thin-walled steel tube and using chemical etching to form the stent pattern. As indicated in an ACS Multi-Link product brochure, "[t]he ACS MULTI-LINK stent is cut from a single stainless steel cylinder." (Exh. D). A different brochure describes the stent as being "thin" and having a "reduced stent profile." (Exh. E). Guidant's web page describes the stent as a "latticed stainless steel tube." (Exh. I). Guidant's press release describes the stent as being made "from a single stainless steel tube." (Exh. J). The final strut thickness of the stent is approximately 0.002 inches. (Exh. E).

and a wall surface disposed between the first and second ends.

The ACS Multi-Link stent has a wall surface located between its two ends

the wall surface having a substantially uniform thickness

The wall surface of the ACS Multi-Link stent has a substantially uniform thickness.

and a plurality of slots formed therein,

The '762 patent defines a slot as being any opening whose length is substantially greater than its width. '762 patent, col. 7, lines 17-20. Two examples of slots "82" are given in the '762 patent, complete slots which are closed, and half-slots which have an open end. See, e.g., '762 patent, col. 7, lines 7-13. Thus, the generic term "slot", as used in the '762 patent, covers both complete slots and half-slots. The wall surface of the ACS Multi-Link stent includes a plurality of slots. The slots are the generally U-shaped segments of the stent whose lengths are substantially greater than their widths. See Exh. K.

the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

As the drawing in Exh. K illustrates, the slots of the ACS Multi-Link stent are substantially parallel to the longitudinal axis of the stent.

and the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen;

Prior to expansion, the ACS Multi-Link stent is sized to a first diameter to allow it to be delivered into and through an access artery and, ultimately, to the coronary arteries. (Exhs. G, I). As indicated in an ACS case report, doctors are able to place an

unexpanded Multi-Link stent, i.e., a stent having a first diameter, through an access artery and deliver the stent to the site of a lesion in a coronary artery. (Exh. F).

the tubular member having a second, expanded and deformed diameter,

The ACS Multi-Link stent has a second diameter after it is expanded and plastically deformed. The second diameter is shown in the ACS Multi-Link stent users' guide. (Exh. G).

upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member,

The ACS Multi-Link stent comes premounted on a balloon catheter. (Exhs. F, G). A "membrane" is located between the balloon and the stent. The membrane is said to cause a uniform radial and outward force to be applied to the interior of the stent. The function of the elastic membrane is said to "distribute[] the balloon force evenly – ensuring complete concentric expansion of balloon and stent." (Exh. D). Another brochure describes the "[p]roprietary balloon system [as] ensur[ing] full cylindrical expansion." (Exh. E).

The expansion of the balloon causes the stent to expand to its second diameter. By varying the amount of pressure applied to the stent through the delivery balloon, a physician can control the expansion of the ACS Multi-Link stent. The physician can shape the stent so that it matches the configuration of the coronary artery at the desired location within that artery. As indicated in the users' guide, the amount of expansion is variable and dependent on the pressure exerted by the deployment balloon on the stent. (Exh. G).

whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

When the Multi-Link stent is expanded and deformed, it expands the lumen of the body passageway, i.e., the purpose of stenting. For example, as indicated in the case report, the use of the Multi-Link stent expanded the lumen of a coronary artery from a residual stenosis of 71% to a 27% stenosis post-stent deployment. Six month later, the residual stenosis remained at 28%. (Exh. F). That describes the purpose of stenting.

11. The ACS Multi-Link stent also contains all of the additional elements of claim 23 of the '762 patent.

Claim 23 **The expandable intraluminal vascular graft of claim 13,**

See claim 13, paragraph 10 above.

wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

From the information at my disposal, it appears that prior to expansion the outside of the ACS Multi-Link stent has a smooth surface.

12. The ACS Multi-Link stent contains all of the elements of claim 24 of the '762 patent.

Claim 24 **An expandable prosthesis for a body passageway, comprising:**

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; an

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

The difference between claims 13 and 23 and claims 24 and 34 is that in the latter the device is described as an "expandable prothesis" as opposed to an "expandable intraluminal vascular graft." An expandable prothesis includes, but is not limited to, an "expandable intraluminal vascular graft." Since the ACS Multi-Link stent is an "expandable intraluminal vascular graft," it is also an expandable prosthesis for use in a body passageway. See claim 13, paragraph 10 above.

Claim 34 **The expandable prosthesis of claim 24, wherein the outside of the wall surface, of the tubular member is a smooth surface, when the tubular member has the first diameter.**

See claim 23, paragraph 11 above.

THE ACS MULTI-LINK STENT INFRINGES CLAIMS 1-3, 9, 11-13, 17, AND 22 OF THE '417 PATENT

13. The ACS Multi-Link stent contains all of the elements of claim 1 of the '417 patent.

Claim 1 **A method for implanting a plurality of prostheses within a body passageway comprising the steps of:**

The ACS Multi-Link stent has 12 ring sections. Each of those sections is a prosthesis which, when placed in a body passageway and expanded, maintains the opening of the body passageway. For example, the ACS '955 patent (Col. 4, lines 48-49), which is marked on the Multi-Link stent users' guide according to 35 U.S.C. § 287(a), indicate that each ring section can expand to a different diameter. (Exh. H). Additionally, ACS describes the Multi-Link stent as being "composed of multiple rings connected to multiple links." (Exh. D).

disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other;

ACS manufacturers the stent so that the adjacent ring prostheses are connected to each other by connectors. Those connectors are integrally formed with the ring prostheses. The connectors disposed between the Multi-Link rings provide the stent with flexibility. That point is highlighted in different ACS brochures. For example, one ACS Multi-Link stent brochure describes the structure of the stent as "composed of multiple rings connected to multiple links – a unique design that offers an exceptionally powerful combination of . . . flexibility." (Exh. D). Another ACS brochure states that the "12 rings [are] linked by 33 articulations for flexibility." (Exh. E).

disposing the plurality of connected prostheses upon a catheter;

The ACS Multi-Link stent is disposed on a catheter by ACS. (Exh. G). As indicated by an ACS brochure, the stent is "factory-crimped" on the balloon. (Exh. E).

inserting the prostheses and catheter within the body passageway by catheterization of said body passageway;

This step is performed when a physician inserts the Multi-Link stent in a patient via catheterization. (Exhs. F, G, I).

and providing controllable expansion of at least one of the prostheses at a desired location within the body passageway

The physician can control the degree and speed of expansion of the ACS Multi-Link stent by varying the amount of pressure applied to the stent through the delivery balloon. The expansion of the delivery balloon will expand at least one of the prostheses once the stent has been delivered to a desired location in the body passageway. As indicated in the users' guide, the amount of expansion is variable and dependent on the pressure exerted by the deployment balloon on the stent. (Exh. G).

by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway,

By expanding the balloon portion of the ACS Multi-Link stent, the stent is expanded radially outwardly into contact with the coronary artery during implantation. (Exh. I). A "membrane" is located between the stent and the delivery balloon. The membrane is said to ensure "complete concentric expansion," "full cylindrical expansion," and "radial concentric deployment," (Exhs. D, E), that is, expansion in which the radius of the stent is increasing.

by deforming a portion of the at least one prosthesis with a force in excess of the elastic limit of the portion of the at least one prosthesis

When the use of the ACS Multi-Link stent is expanded by the balloon the stent is plastically and permanently deformed in order for the stent to conform to the interior of the artery (Exh. I). The stent retains its expanded shape and diameter because it is deformed by a force in excess of the elastic limit of the stent.

to implant the prostheses within the body passageway.

When the stent is expanded within the body passageway, it becomes implanted. (Exhs F, G, I).

14. The ACS Multi-Link stent also contains all of the elements of claim 2 of the '417 patent.

Claim 2 The method of claim 1, further including the steps of: collapsing the portion of the catheter associated with the prostheses, and removing the catheter from the body passageway.

The balloon catheter is collapsed and withdrawn once a physician has expanded and implanted the ACS Multi-Link stent. (Exhs. G, I).

15. The ACS Multi-Link stent contains all of the elements of claim 3 of the '417 patent.

Claim 3 **The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.**

The ACS Multi-Link stent comes placed on an expandable, inflatable balloon portion of a catheter. (Exh. I). When a physician inflates the balloon, the balloon portion of the catheter expands and exerts a radially, outwardly force on the stent. (Exh. I). That force causes the stent to expand and deform. (Exhs. F G).

16. The ACS Multi-Link stent contains all of the elements of claim 9 of the '417 patent.

Claim 9 **The method of claim 1, wherein a thin-walled, tubular member is utilized as each prosthesis,**

Each ring of the ACS Multi-Link stent is a thin-walled tubular member which functions as a prosthesis. From the information I have reviewed, it appears that the ACS Multi-Link stent is manufactured by taking a thin-walled steel tube and using chemical etching to form the stent pattern. As indicated in an ACS Multi-Link product brochure, "[t]he ACS MULTI-LINK stent is cut from a single stainless steel cylinder." (Exh. D). A different brochure describes the stent as being "thin" and having a "reduced stent profile." (Exh. E). Guidant's web page describes the stent as a "latticed stainless steel tube." (Exh. I). Guidant's press release describes the stent as being made "from a single stainless steel tube." (Exh. J). The final strut thickness of the stent is approximately 0.002 inches. (Exh. E).

each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member.

The term "slot" is used in the '417 patent to describe an opening whose length is substantially greater than its width. Two examples of slots "82" are given in the '417 patent, complete slots which are closed, and half-slots which have an open end. See, e.g., '417 patent, col. 7, lines 53-59. Thus, the generic term "slot," as used in the '417 patent, covers both closed and open-ended slots.

The wall surface of the ACS Multi-Link stent has a plurality of slots. Those slots are the generally U-shaped segments of the stent whose lengths are substantially greater than their widths. The slots are substantially parallel to the longitudinal axis of the prosthesis. The slots are indicated in Exhibit K.

17. The ACS Multi-Link stent contains all of the elements of claim 11 of the '417 patent.

Claim 11 **The method of claim 9, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of each tubular member,**

As the drawing in Exhibit K illustrates, the slots of each prosthesis of the ACS Multi-Link stent are uniformly and circumferentially spaced from adjacent slots and are also uniformly and circumferentially spaced from adjacent slots along the longitudinal axis.

whereby at least one elongate member is formed between adjacent slots.

An elongate member is a member which is longer than it is wide. The member between each of the adjacent slots of the Multi-Link is substantially longer than it is wide. See Exhibit K.

18. The ACS Multi-Link stent contains all of the elements of claim 12 of the '417 patent.

Claim 12 The method of claim 11, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

Upon information and belief, the thin-walled tubular members and the elongate members of the ACS Multi-Link stent have the same wall thickness. See Exhibit K.

19. The ACS Multi-Link stent contains all of the elements of claim 13 of the '417 patent.

Claim 13 The method of claim 9, wherein each thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway

Upon expansion of the balloon portion of the catheter within a body passageway, each ring prosthesis is expanded and plastically deformed to a second diameter. As discussed above in claim 1 (paragraph 13), by varying the amount of pressure applied to the stent through the delivery balloon, a physician can control the

expansion of the ACS Multi-Link stent. Through that process, the physician can shape the stent so that it matches the configuration of a body passageway at the desired location within that artery.

whereby each expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of each thin-walled tubular member does not cause a rupture of the body passageway.

To work properly and safely as a stent, upon expansion, the ACS Multi-Link stent must be securely placed in the body passageway so that it does not migrate. Additionally, the stent should not be expanded so large as to rupture the body passageway. (Exh. G).

20. The ACS Multi-Link stent contains all of the elements of claim 17 of the '417 patent.

Claim 17 **A method for expanding the lumen of a body passageway comprising the steps of:**

The ACS Multi-Link stent is used to expand the lumen of a body passageway, such as an artery.

connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts

The ACS Multi-Link stent has 12 ring sections. Each of those sections is a vascular "graft" which, when placed in a body passageway and expanded, expands the lumen of the body passageway. For example, the ACS '995 patent (Col. 4, lines 48-49), which is marked on the Multi-Link stent users' guide according to 35 U.S.C. § 287(a),

indicates that each ring section can be expanded to a differenf diameter. (Exh. H). Additionally, ACS describes the Multi-Link stent as being "composed of multiple rings connected to multiple links." (Exh. D).

ACS manufacturers the stent so that the adjacent rings are connected to each other by connectors. Those connectors are integrally formed with the rings. The connectors disposed between the Multi-Link rings provide the stent with flexibility. That point is highlighted in different ACS brochures. One ACS Multi-Link stent brochure describes the structure of the stent as "composed of multiple rings connected to multiple links – a unique design that offers an exceptionally powerful combination of . . . flexibility." (Exh. D). Another ACS brochure states that the "12 rings [are] linked by 33 articulations for flexibility." (Exh. E).

inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway;

ACS manufacturers the ACS Multi-Link system with the stent on a catheter. A physician using the stent inserts it into the body passageway until the stent is adjacent a desired location within the body passageway. (Exhs. G, I).

and expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway,

See claim 1, paragraph 13 above.

by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the ir. aluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded,

See claim 1, paragraph 13 above.

whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen,

The expanded ACS Multi-Link stent provides structural support to and prevents the walls of the body passageway from collapsing. (Exh. F, I). That is the purpose of stenting

and the intraluminal rafts [sic, grafts] remain in the passageway.

The ACS Multi-Link stent remains in the coronary artery once it is implanted. (Exh. I).

21. The ACS Multi-Link stent contains all of the elements of claim 22 of the '417 patent.

Claim 22 The method of claim 17, wherein a thin-walled tubular member is utilized as each intraluminal graft,

See claim 9, paragraph 16 above.

each tubular member having a plurality of slots formed therein,

See claim 9, paragraph 16 above.

the slots being disposed substantially parallel to the longitudinal axis of the tubular members.

See claim 9, paragraph 16 above.

22. The ACS Multi-Link stent contains all of the elements of claim 25 of the '417 patent.

Claim 25 **An expandable intraluminal vascular graft, comprising:**

The ACS Multi-Link stent is an "intraluminal vascular graft" as defined in the '417 Patent and as I understand the term. The ACS Multi-Link stent can be expanded by a balloon.

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends,

See claim 17, paragraph 20 above

the wall surface having a substantially uniform thickness and

The wall surface of the Multi-Link stent has a substantially uniform wall thickness.

a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

See claim 9, paragraph 16 above.

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

See claim 1, paragraph 13 above.

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

Prior to expansion, the ACS Multi-Link stent is sized to a first diameter to allow it to be delivered into and through an access artery and, ultimately, to the coronary arteries. (Exhs. G, I). As indicated in an ACS case report, doctors are able to place an

unexpanded Multi-Link stent, i.e., a stent having a first diameter, through an access artery and deliver the stent to the sight of a lesion in a coronary artery. (Exh. F).

the tubular members having a second, expanded and deformed diameter,

The ACS Multi-Link stent has a second diameter after it is expanded and plastically deformed.

upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members,

The ACS Multi-Link stent comes premounted on a balloon catheter. A membrane located between the balloon and the stent causes a uniform radial and outward force to be applied to the interior of the stent. That feature is highlighted in various ACS brochures. One brochure describes the function of the elastic membrane to "distribute[] the balloon force evenly – ensuring complete concentric expansion of balloon and stent." (Exh. D). Another brochure describes the "[p]roprietary balloon system [as] ensur[ing] full cylindrical expansion." (Exh. E)

The expansion of the balloon causes the stent to expand to its second diameter. By varying the amount of pressure applied to the stent through the delivery balloon, a physician can control the expansion of the ACS Multi-Link stent. The physician can shape the stent so that it matches the configuration of the coronary artery at the desired location with that artery. As indicated in the users' guide, the amount of expansion is variable and dependent on the pressure exerted by the deployment balloon on the stent. (Exh. G).

whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

When the Multi-Link stent is expanded and deformed, it expands the lumen of the body passageway. As indicated in the case report, the use of the Multi-Link stent expanded the lumen from a residual stenosis of 71% to a 27% stenosis post-stent deployment. Six month later, the residual stenosis remained at 28%. (Exh. F). That describes the purpose of stenting.

23. The ACS Multi-Link stent contains all of the elements of claim 29 of the '417 patent.

Claim 29 **An expandable prosthesis for a body passageway, comprising:**

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

The difference between claim 25 and claim 29 is that in the latter the device is described as an "expandable prothesis" as opposed to an "expandable intraluminal vascular graft." An expandable prothesis includes, but is not limited to, an expandable

intraluminal vascular "graft." Since the ACS Multi-Link stent is an "expandable intraluminal vascular graft," it is also an expandable prosthesis for use in a body passageway. See claim 26, paragraph 22 above.

24 I declare under penalty of perjury that the foregoing is true and correct.

Dated: Bonita Spring, Florida
October 7, 1997

Lee P. Bendel

CV - Lee P. Bendel
August 26, 1997

Education and Relevant Work Experience

Education

Lehigh University
Metallurgical Engineering
B.S., 1962

Lehigh University
Metallurgical Engineering
M.S., 1966

Experience

1962-1965 Carpenter Technology Corporation
Research Center, Reading, PA
Research Metallurgist

1966-1969 Carpenter Technology Corporation
Corporate Headquarters, Reading, PA
Manager Stainless Steel Metallurgy

1969-1994 Ethicon, Inc. Somerville, NJ

1969-1972 Senior Development Engineer
1972-1976 Supervisor, Needle Development
1976-1980 Manager, Specialty Manufacturing
1980-1993 Manager, Materials Engineering
1993-1994 Senior Engineering Fellow

1994-Present Materials Technology Associates Inc., Lebanon, NJ
Vice-president

Publications and Patents

"Ophthalmic Needles, An Engineering Analysis", Supplement to OPHTHALMOLOGY, Vol.93, No.9, Sept. 1986. (a cited article).

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4449530	Metallic, Hemostatic Clips providing a reduced gap when closed about a tubular vessel.
4660559	A unitary sterile surgical needle having a hardened cutting edge a malleable center portion.
4905695	Sterile surgical needle having dark non-reflective surface.
4959063	Sterile surgical needle having dark non-reflective surface.
5000912	Nickel titanium martensitic steel for surgical needles.
5219358	Shape Memory Effect Surgical Needles.
5242458	Suture needle holder for endoscopic use.
5341815	Endoscopic Surgical Pouch
5350419	Cardiac Pacing lead
5415707	High Modulus Materials for Surgical Needles

Awards and Societies

Fellow - American Society of Metals International

Philip B. Hoffman Research Scientist Award - This award was presented by Mr. Hoffman, CEO of J&J for outstanding technical effort in the introduction of ASTM 45500 Cardio-Vascular needles.

Served on several specification writing committees of ASTM

Voting member of the F4 Committee (Medical Devices and Standards) of the ASTM

Session Chairperson - Product Safety and Liability, Prevention for the Medical Device Industry, University of Wisconsin

Member American Society for Metals. Wire Association, The Minerals, Metals, & Materials Society

United States Patent [19]

Palmaz

[11] Patent Number: 4,739,762

[45] Date of Patent: Apr. 26, 1988

[54] EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

[75] Inventor: Julio C. Palmaz, San Antonio, Tex.

[73] Assignee: Expandable Grafts Partnership, San Antonio, Tex.

[21] Appl. No.: 923,796

[22] Filed: Nov. 3, 1986

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 794,008, Nov. 7, 1985.

[51] Int. Cl.[4] A61M 29/00

[52] U.S. Cl. 128/343; 604/104; 604/96; 623/1

[58] Field of Search ..... 604/93, 49, 263, 97; 623/1; 128/344, 343, ; R

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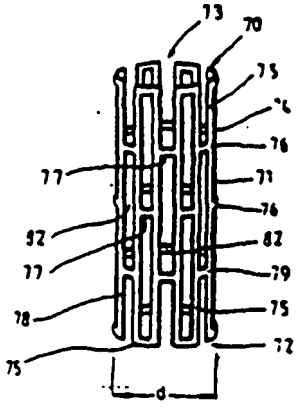
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Gene B. Kartchner
Attorney, Agent, or Firm—Ben D. Tobor

[57] ABSTRACT

An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a thin-walled tubular member having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular member.

43 Claims, 3 Drawing Sheets



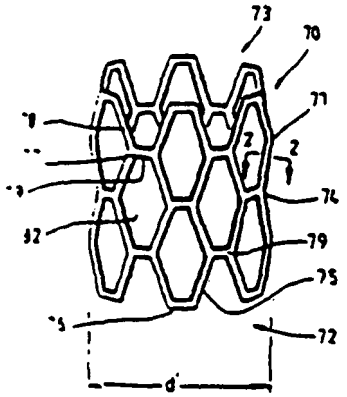


Fig. 2

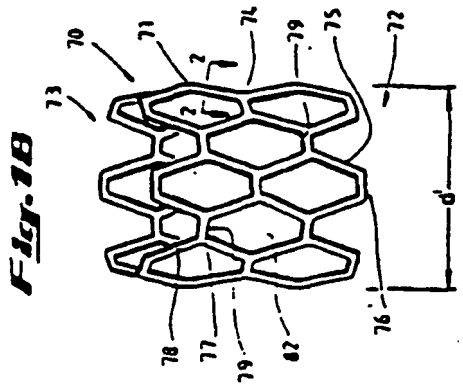


Fig. 1B

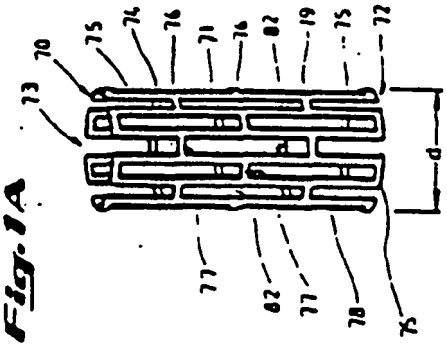
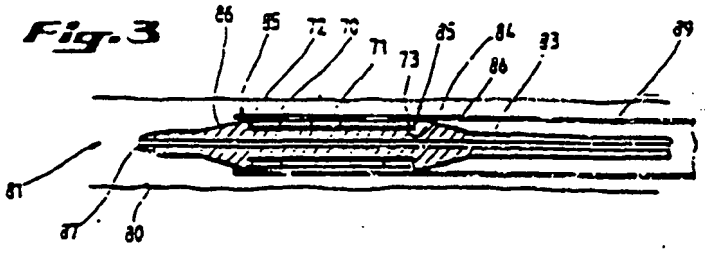


Fig. 1A

Fig. 3



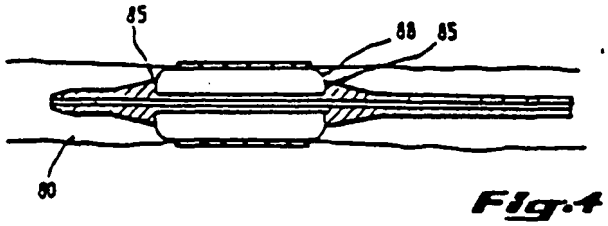
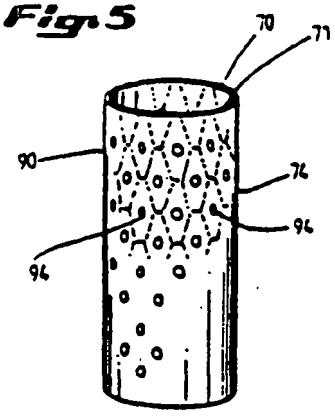


Fig. 4

Fig. 5



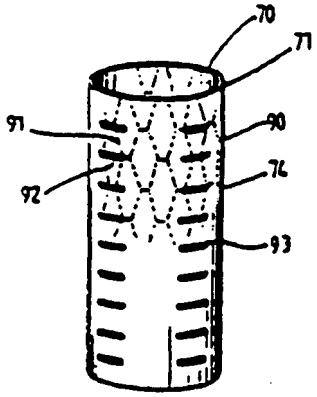


Fig. 6

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part of Applicant's co-pending application Ser. No. 06/794,009 filed Nov. 7, 1985 entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

This invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART.

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermined the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic structures and postendar-

frequently recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular shaped member having a first diameter which permits intraluminal delivery of the thin-walled tubular member into a body passageway having a lumen; and the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member. An additional feature of the present invention is that the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter. A further feature of the present invention is that the tubular shaped member may have a biological inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a prosthesis within a body passageway. The method of the present invention comprises the steps of: utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; disposing the prosthesis upon a catheter; inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and expanding and deforming the prosthesis to a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

A further feature of the present invention is that the portion of the catheter in contact with the prosthesis may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: an expandable and deformable, thin-walled tubular prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prosthesis on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prosthesis.

The expandable intraluminal vascular graft, method for implanting a prosthesis within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of

stances: it is believed to permit implantation of grafts in internal body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2–2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configurations shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B; and

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION:

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention. Also as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support. (2) similar use following catheter passage through occluded and other veins occluded by inoperable cancers; (3) reinforcement of cathether created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77 which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed

intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired. Use of the term "slot" encompasses an opening whose length is substantially greater than its width, such as an elongated oval opening.

The foregoing described construction of graft, or prosthesis, 70 permits graft, or prosthesis, 70 to be expanded uniformly, and outwardly, into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prosthesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 76 of graft, or prosthesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prosthesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prosthesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The forces to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prosthesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prosthesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any outward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, or prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

in a conventional manner, the catheter 83 and graft or prosthesis 70 are delivered to the desired location within the body passageway 80, wherein it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70 or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis 70 are delivered to the desired location within the body passageway. Prosthesis or graft, 70 is then expanded and deformed by expanding the expandable, inflatable portion 84 of catheter 82, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon TM sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not constantly applying an outward, radial force against the interior surface of body passageway 80 in excess of that required to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, wherein vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear, close and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the lumen or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. For example, the means for expanding the prosthesis or graft could be a plurality of hydraulically actuated rigid members disposed on a catheter, or a plurality of angioplasty balloons could be utilized to expand the prosthesis or graft. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

I claim:

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

2. The method of claim 1, further including the step of: collapsing the portion of the catheter associated with the prosthesis, and removing the catheter from the body passageway.

3. The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim 1, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

5. The method of claim 4, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

6. The method of claim 5, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

7. The method of claim 1, wherein the thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby the expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of the thin-walled tubular member does not cause a rupture of the body passageway.

8. The method of claim 7, wherein the thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

9. The method of claim 1, wherein the thin-walled tubular member is provided with a biologically inert coating on the outer surface of the thin-walled tubular member.

10. The method of claim 9, wherein the coating is provided with a means for anchoring the prosthesis to the body passageway.

11. The method of claim 10, wherein the means for anchoring is the coating being provided with a plurality of radially, outwardly extending projections for engagement with the body passageway.

12. The method of claim 9, wherein the coating is provided with a plurality of openings to allow communication between the body passageway and the interior of the thin-walled tubular member.

13. An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

14. The expandable intraluminal vascular graft of claim 13, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

15. The expandable intraluminal vascular graft of claim 14, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

16. The expandable intraluminal vascular graft of claim 13, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

17. The expandable intraluminal vascular graft of claim 13, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. The expandable intraluminal vascular graft of claim 13, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. The expandable intraluminal vascular graft of claim 13, wherein the tubular member has a biologically inert coating on the wall surface.

20. The expandable intraluminal vascular graft of claim 19, wherein the coating includes a means for anchoring the tubular member to the body passageway.

21. The expandable intraluminal vascular graft of claim 20, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

22. The expandable intraluminal vascular graft of claim 19, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

24. An expandable prosthesis for a body passageway, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

25. The expandable prosthesis for a body passageway of claim 24, wherein the tubular member has a biologically inert coating on the wall surface.

26. The expandable prosthesis for a body passageway of claim 25, wherein the coating includes a means for anchoring the tubular member to the body passageway.

27. The expandable prosthesis for a body passageway of claim 26, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

28. The expandable prosthesis for a body passageway of claim 25, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

29. The expandable prosthesis of claim 24, wherein the the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

30. The expandable prosthesis of claim 29, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

31. The expandable prosthesis of claim 24, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

32. The expandable prosthesis of claim 24, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

33. The expandable prosthesis of claim 24, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

34. The expandable prosthesis of claim 24, wherein the outside of the wall surface, of the tubular member is a smooth surface, when the tubular member has the first diameter.

35. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim 35, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable, tubular prosthesis.

37. An apparatus for expanding the lumen of a body passageway comprising:

an expandable and deformable thin-walled intraluminal vascular graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the graft; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular graft on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular graft is expanded and deformed radially outwardly into contact with the body passageway.

38. The apparatus of claim 37, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable intraluminal vascular graft.

39. The method of claim 1, wherein tantalum is utilized for the tubular member.

40. The expandable intraluminal vascular graft of claim 13, wherein tantalum is utilized for the tubular member.

41. The expandable prosthesis of claim 24, wherein tantalum is utilized for the tubular member.

42. The apparatus of claim 35, wherein tantalum is utilized for the tubular prosthesis.

43. The apparatus of claim 37, wherein tantalum is utilized for the intraluminal vascular graft.

* * * * *

US005102417A

United States Patent [19]

Palmaz

[11] Patent Number: 5,102,417

[45] Date of Patent: Apr. 7, 1992

[54] EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

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[73] Assignee: Expandable Grafts Partnership, San Antonio, Tex.

[21] Appl. No.: 174,346

[22] Filed: Mar. 28, 1988

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 923,796, Nov. 3, 1986, Pat. No. 4,739,762, which is a continuation-in-part of Ser. No. 794,029, Nov. 7, 1985, Pat. No. 4,733,665.

[51] Int. Cl.[5] A61M 5/00; A61F 2/02

[52] U.S. Cl. 606/195; 604/8; 604/96; 604/282; 623/11

[58] Field of Search 128/343, 344; 604/93, 604/49, 282, 283, 97, 8, 283; 623/1, 12, 11; 606/191-195, 108

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Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Mark Bockelman
Attorney, Agent, or Firm—Ben D. Tobor

[57] ABSTRACT

A plurality of expandable and deformable intraluminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The grafts may be thin-walled tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members, and adjacent grafts are flexibly connected by at least one connector member.

36 Claims, 3 Drawing Sheets

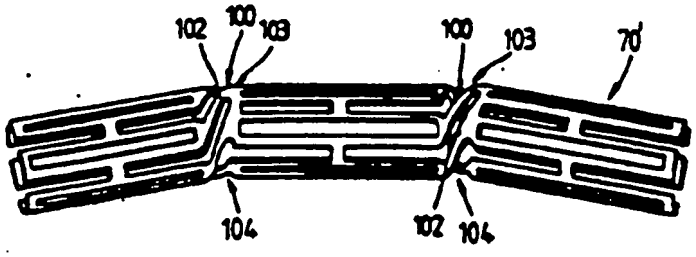


FIG.2

FIG.1B

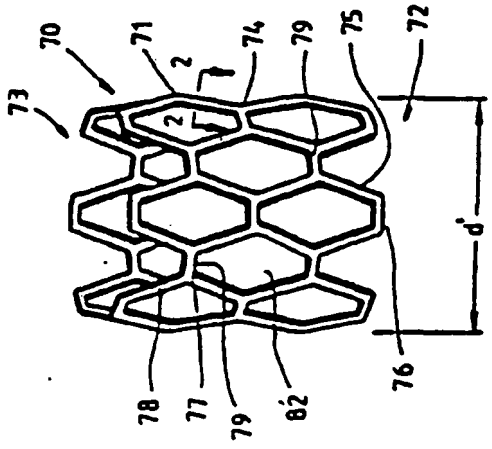


FIG.1A

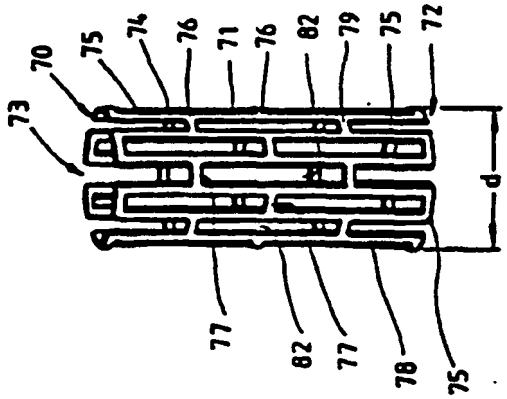
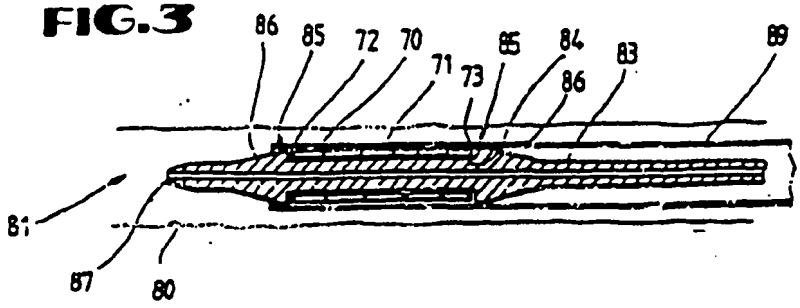


FIG.3



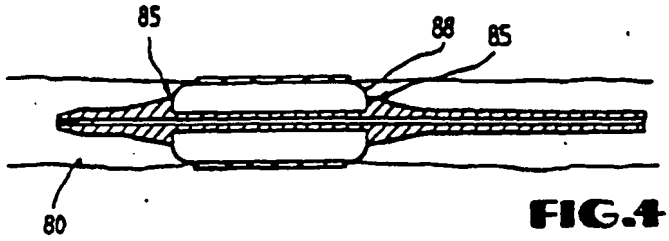
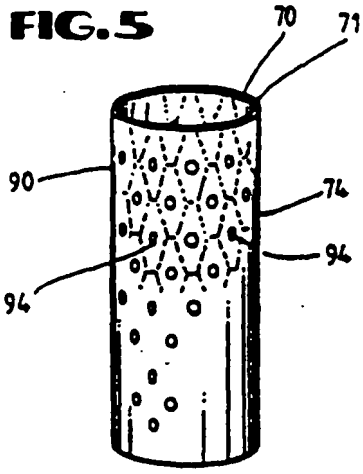


FIG.4

FIG.5



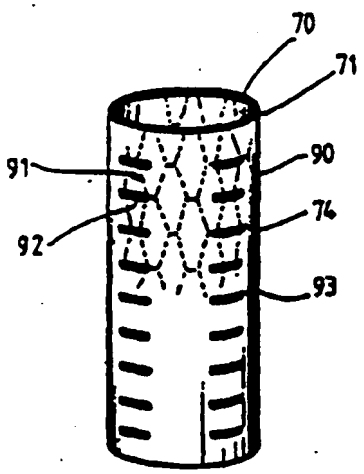


FIG.6

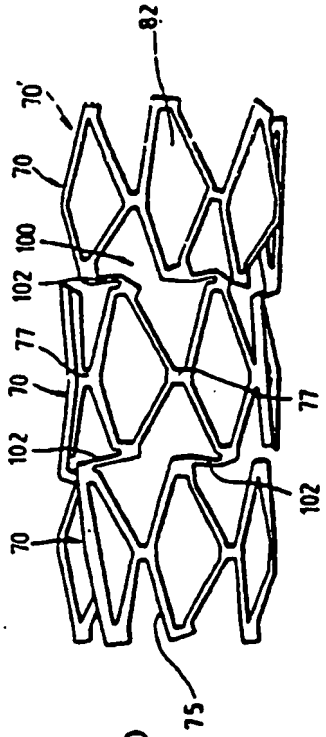


FIG.10

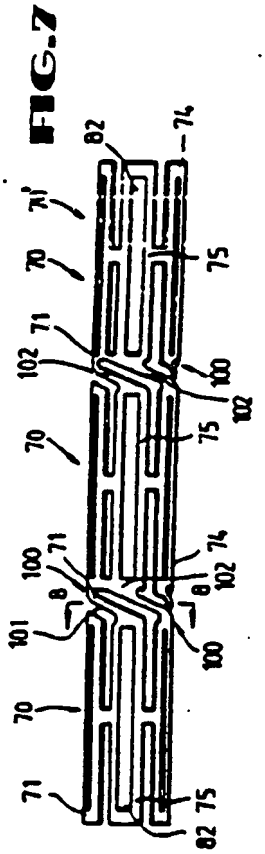


FIG.7

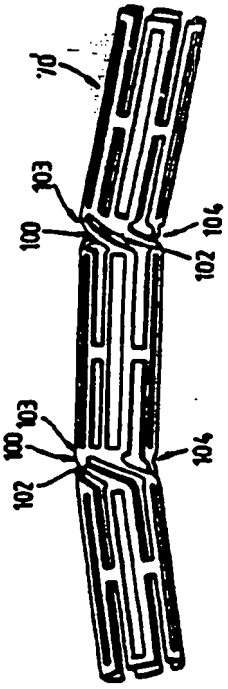


FIG.9

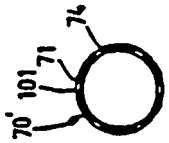


FIG.8

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part application of Applicant's co-pending application, Ser. No. 923,798 now U.S. Pat. No. 4,739,762, filed Nov. 3, 1986, which application is a continuation-in-part of Applicant's co-pending application, Ser. No. 06,796,009 now U.S. Pat. No. 4,733,665 filed Nov. 7, 1985, entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of such structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and distrust the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly closes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedure could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by anastomal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty

of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrous nature of these lesions.

For repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway through which the graft is passed by the catheter. In other words, in many instances, it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location and prevents rupturing and/or erosion of the body passageway by the expanded graft; permits intima of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft; permits intima of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a plurality of thin-walled tubular members having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; each tubular member having a first diameter which permits intraluminal delivery of the thin-walled tubular members into a body passageway having a lumen; and the tubular members having a second, expanded diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular shaped members may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Another feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members. An additional feature of the present invention is that at least one connector member may be a thin-walled, spiral member, coplanar with adjacent tubular members.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a plurality of prostheses within a body passageway. The method of the present invention comprises the steps of: disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other; disposing a plurality of connected prostheses upon a catheter; inserting the prostheses and catheter within the body passageway by catheterization of the body passageway; and providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prostheses with a force in excess of the elastic limit of the portion of the at least one prostheses, to implant the prostheses within the body passageway.

A further feature of the present invention is that the portion of the catheter in contact with the prostheses may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that a thin-walled tubular member may be utilized as each prostheses, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member. Another feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one connector member is formed between adjacent slots.

Another feature of the present invention is that the at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent prostheses. A further feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular member. A further feature of the present invention is that the at least one connector member may be formed as a thin-walled, spiral member, coplanar with adjacent tubular members.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prostheses on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prostheses.

The expandable intraluminal vascular graft, method for implanting a plurality of prostheses within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; permits expansion of the graft to a variable size dependent upon conditions within the body passageway; permits times of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2—2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B;

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;

FIG. 7 is a front view of another embodiment of a graft or prosthesis in accordance with the present invention;

FIG. 8 is a cross-sectional view of the graft, taken along line 8—8 of FIG. 7.

FIG. 9 is a perspective view of the graft of FIG. 7, wherein the graft has been bent or articulated; and

FIG. 10 is a perspective view of the graft of FIG. 7, after the graft has been expanded and deformed.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of catheter created intrahepatic communications between portal and hepatic veins in persons suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the stenoma, the urinary, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, as be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and

dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 72. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, each half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

The foregoing described construction of graft, or prosthesis, 70 permits graft, or prosthesis, 70 to be expanded uniformly, and outwardly, in a controlled manner into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prosthesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prosthesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prosthesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prosthesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 71, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prosthesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prosthesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any out-

ward, radial force, as that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, or prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, wherein it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then controllably expanded and deformed by controllably expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon TM sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is controllably expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4, and by the amount of expansion of the inflatable portion 84 of catheter 83. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80, in excess of that required to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor will loose end flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid,

maluccentic endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert or biologically compatible coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prostheses, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area. Examples of biologically compatible coatings 90 would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycolides, polylactoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating 90 is absorbed, or dissolves, the drug would be slowly released into the body passageway 80.

Turning now to FIGS. 7–10, an expandable intraluminal vascular graft, or prosthesis, 70' is shown for implantation in curved body passageways 80, or for use in elongated sections of body passageway 80, when a prosthesis, or graft, 70' is required which is longer than the grafts, or prostheses, 70 of FIG. 1A. Identical reference numerals are used throughout FIGS. 7–10 for elements which are the same in design, construction, and operation, as those previously described in connection with FIGS. 1A–6, and primed reference numerals are used for elements which are similar in construction, design, and operation, as those previously described in connection with FIGS. 1A–6.

As seen in FIG. 7, graft, or prosthesis, 70' generally includes a plurality of prostheses, or grafts 70 as described previously in connection with FIGS. 1A, 1B, and 2. Preferably, the length of each graft, or prosthesis, 70 is approximately the length of one slot 82, however, the length of each graft 70 could be approximately equal to the length of two slots 82, as illustrated in FIG. 1A. Disposed between adjacent tubular members, 71, or adjacent grafts, or prostheses, 70, is at least one connector member 100 to flexibly connect adjacent tubular members 71, or grafts, or prostheses, 70. Connector member, or members, 100 are preferably formed of the same materials as grafts 70, as previously described, and connector members 100 may be formed integrally between adjacent grafts 70, or tubular members, 71 as shown in FIG. 7. As seen in FIG. 8, the cross-sectional configuration of connector member, or members, 100, along the longitudinal axis of graft, or prosthesis 70', is the same, in that connector member, or members, 100 have the same uniform wall thickness of elongate members 73. Of course, it should be readily apparent to one of ordinary skill in the art, that the thickness of connector members 100 could alternatively be smaller than that of elongate members 73, however, it is preferable that the outer circumferential surface 101 of connector members 100 lies in the same plane formed by the wall surface 74 of grafts, or prostheses 70, as seen in FIG. 8.

Still with reference to FIGS. 7–8, connector members 100 are preferably disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent grafts, or prostheses, 70. Further, it is preferable that the at least one connector member 100 is formed as a thin-walled spiral member 102 which is coplanar with the outer wall surface 74 of the adjacent tubular members 71, or adjacent grafts, or prostheses, 70. It should be noted that although graft, or prosthesis, 70' is illustrated as including three grafts, or prostheses, 70 flexibly connected to one another by connector members 100, as few as two grafts 70 could be connected to form graft, or prosthesis, 70'. Furthermore, many grafts 70 could be flexibly connected by connector members 100 as are desired to form graft, or prosthesis, 70'.

The delivery and expansion of graft or prosthesis, 70' is the same as that previously described in connection with FIGS. 1A, 1B, and 3–4. The length of the expandable, inflatable portion 84 of catheter 83 would be sized to conform with the length of graft, or prosthesis, 70', as should be readily apparent to one of ordinary skill in the art. Except for the length of the expandable, inflatable portion 84 of catheter 83, the method of delivery of graft, or prosthesis, 70' and its subsequent, controllable expansion and deformation is the same as previously described.

With reference to FIG. 9, the prosthesis 70' is illustrated in the configuration it would assume when being delivered to the desired location within the body passageway 80 and the graft, or prosthesis, 70' is disposed upon catheter 83 and is passing through a curved portion of body passageway 80, such as an arterial bend. For clarity, catheter 83 is not shown in FIG. 9, since the flexibility of such catheters 83 is well known in the art. As seen in FIG. 9, because of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prostheses, 70, graft, or prosthesis, 70' is able to flexibly bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways 80. As seen in FIG. 9, as graft, or prostheses, 70' bends, or articulates about the longitudinal axis of graft 70', the spacing between tubular members 71 increases, or expands, about the outer side of the curve, or bend, 103; and the spacing decreases, or is compressed, on the inner side of the curve, or bend, 104. Likewise, spiral connector members 102 adjacent the outer side of the curve 103 flexibly and resiliently stretch to permit the expansion of the spacing therein; and the spiral connector members 102 adjacent the inner side of the curve, 104 flexibly and resiliently compress to permit the decrease in the spacing between tubular members 71 on the inner side of curve 104. It should be noted that connector members 100 permit the bending, or articulation, of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70'.

Turning now to FIG. 10, graft, or prosthesis, 70' is illustrated in its expanded, and deformed configuration, similar to that illustrated in FIG. 1B. It should be noted that should it be desired to implant graft, or prosthesis, 70' on a curved portion of a body passageway 80, such

implantation and expansion would be permitted by the connector members 100. It should also be noted that prostheses, or grafts, 70 could be flexibly connected to one another to form a graft, or prosthesis, 70' wherein such grafts, or prostheses, 70 are formed as wire mesh tubes of the type illustrated in Applicant's co-pending application, Ser. No. 06/796,009, filed Nov. 7, 1985, entitled, "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft", which application is incorporated by reference herein.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials, or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

What is claimed is:

1. A method for implanting a plurality of prostheses within a body passageway comprising the steps of:

disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other;

disposing the plurality of connected prostheses upon a catheter;

inserting the prostheses and catheter within the body passageway by catheterization of said body passageway; and

providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prosthesis with a force in excess of the elastic limit of the portion of the at least one prosthesis, to implant the prostheses within the body passageway.

2. The method of claim 1, further including the steps of: collapsing the portion of the catheter associated with the prostheses, and removing the catheter from the body passageway.

3. The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.

5. The method of claim 1, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axes of adjacent prostheses.

6. The method of claim 1, including the step of: utilizing a wire mesh tube as each prosthesis, the wire mesh tubes having a first predetermined collapsed diameter which permits the tubes to be disposed upon the catheter and inserted into the body passageway.

7. The method of claim 6, including the step of disposing the at least one connector member coplanar with each wire mesh tube and non-parallel to the longitudinal axis of the wire mesh tubes.

8. The method of claim 6, wherein tantalum is utilized for the wire mesh tube.

9. The method of claim 1, wherein a thin-walled, tubular member is utilized as each prosthesis, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member.

10. The method of claim 9, wherein tantalum is utilized for the tubular member.

11. The method of claim 9, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one elongate member is formed between adjacent slots.

12. The method of claim 11, wherein the thin-walled tubular member and the elongate members, disposed between adjacent slots have a uniform wall thickness.

13. The method of claim 9, wherein each thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby each expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of each thin-walled tubular member does not cause a rupture of the body passageway.

14. The method of claim 13, wherein each thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

15. The method of claim 9, including the step of disposing the at least one connector member coplanar with each tubular member and non-parallel to the longitudinal axes of the tubular members.

16. The method of claim 9, including the step of forming the at least one connector member as a thin-walled spiral member, coplanar with adjacent tubular members.

17. A method for expanding the lumen of a body passageway comprising the steps of:

connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts;

inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway; and

expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway, by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the intraluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal grafts remain in the passageway.

18. The method of claim 17, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axis of the intraluminal grafts.

19. The method of claim 17, including the step of: utilizing a wire mesh tube as the intraluminal graft, the wire mesh tube having a first predetermined, collapsed diameter which permits the tube to be inserted within the body passageway at the desired location.

20. The method of claim 19, including the step of disposing the at least one connector member coplanar with each wire mesh tube and non-parallel to the longitudinal axis of the wire mesh tubes.

21. The method of claim 19, wherein tantalum is utilized for the wire mesh tube.

22. The method of claim 17, wherein a thin-walled tubular member is utilized as each intraluminal graft, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular members.

23. The method of claim 22, including the step of disposing the at least one connector member coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

24. The method of claim 22, including the step of forming the at least one connector member as a thin-walled spiral member, coplanar with adjacent tubular members.

25. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

26. The expandable intraluminal graft of claim 25, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

27. The expandable intraluminal graft of claim 25, wherein the at least one connector member is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

28. The expandable intraluminal graft of claim 25, wherein the at least one connector member is a thin-walled, spiral member, coplanar with adjacent tubular members.

29. An expandable prosthesis for a body passageway, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

30. The expandable prosthesis of claim 29, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

31. The expandable prosthesis of claim 29, wherein the at least one connector member is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

32. The expandable prosthesis of claim 29, wherein the at least one connector member is a thin-walled, spiral member, coplanar with adjacent tubular members.

33. An apparatus for intraluminally reinforcing a body passageway, comprising:

a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prostheses on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway.

34. The apparatus of claim 33, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent the ends of the expandable, tubular prostheses.

35. An apparatus for expanding the lumen of a body passageway comprising:

a plurality of expandable and deformable thin-walled intraluminal vascular grafts, each graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the grafts, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular grafts on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular grafts are expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim 35, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent the ends of the expandable intraluminal vascular grafts.

* * * * *

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MULTI LINK

ACS® MULTI-LINK® CORONARY STENT SYSTEM

Flexibility
Strength
Conformability

SPECIFICATION

The ACS MULTI-LINK stent is cut from a single stainless steel cylinder. Its distinctive, intricate structure is composed of multiple rings connected to multiple links – a unique design that offers an exceptionally powerful combination of radial strength, flexibility and conformability.

The MULTI-LINK is a balloon expandable stent. It is 15mm long with minimal shortening on expansion.

To accommodate vessels of varying diameters, the MULTI-LINK stent has been mounted on a versatile delivery system incorporating a wide selection of low-profile, low-compliant PE 600® balloons. Each balloon carries distal and proximal markers to aid positioning and deployment.

Between the MULTI-LINK and the balloon is a specially designed elastic membrane which distributes the balloon force evenly – ensuring complete concentric expansion of balloon and stent and producing a streamlined profile on retraction.

A flexible, retractable sleeve covers the entire catheter – including the stent and balloon section of the delivery system. In this way, both the stent and the artery are fully protected whilst MULTI-LINK is being manoeuvred through the coronary anatomy to its ultimate destination.

Stent Sizes Available	Stock No.	Stent Length	Sleeve Crossing Profile	Nominal Shaft Diameter Distal/Proximal	Minimal Internal Diameter of Guiding Catheter	Maximum Guide Wire	Shaft Working Length	Rated Burst Pressure
3.0mm	600110	15 mm	.068 in	3.0/3.6Fr*	.079 in*	.014 in	135 cm	6 atm
3.25mm	600111	15 mm	.068 in	3.0/3.6Fr*	.079 in*	.014 in	135 cm	8 atm
3.5mm	600112	15 mm	.068 in	3.0/3.6Fr*	.079 in*	.014 in	135 cm	8 atm

*For sheaths with flow-restrictive valves

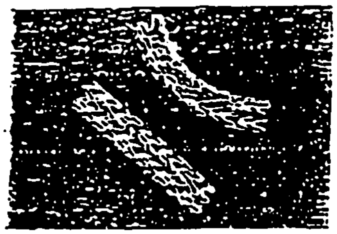
AS®

[redacted]

An exceptional start. A smooth delivery. An excellent choice.

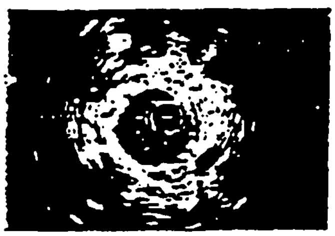
GUIDANT

Coronary Stent System



Strength and flexibility combined
Conformable stainless steel tubular design

- 12 rings linked by 33 articulations for flexibility
- thorough wall coverage with minimal metal
- thin .002" struts for reduced stent profile



Easy and accurate delivery
Safe 5F-compatible systems

- factory-crimped stent for added security
- distal and proximal balloon markers for accurate stent positioning
- stent deploys uniformly to nominal size at 6 atm

1. Elastic membrane 2. Stent
3. Stent 4. Balloon

Radial concentric deployment
Proprietary balloon system ensures full cylindrical expansion and easy retraction

- propeller folded balloon wrapped in an elastic membrane distributes inflation force evenly for optimal strut apposition to the artery wall
- high-conforming PE-600 balloon for uniform deployment in tortuous anatomy
- elastic membrane streamlines balloon refold for smooth system withdrawal

Stent Sizes Available	[illegible]	Stent Length	[illegible]	[illegible]	[illegible]	[illegible]	Rated Burst Pressure
3.0 mm	[illegible]	15 mm	[illegible]	[illegible]	.014 in	[illegible]	[illegible]
3.5 mm	[illegible]	15 mm	[illegible]	[illegible]	.014 in	[illegible]	[illegible]
4 mm	[illegible]	15 mm	[illegible]	[illegible]	.014 in	[illegible]	[illegible]

[illegible]

MULTI LINK

Acute dissection repair, post angioplasty in a right coronary artery using the ACS MULTI-LINK® coronary stent system.

FIGS. 1A & 1B LAO and RAO views showing a tortuous LCA with Shepherd's Crook takeoff. The lesion was proximal. The stenosis was to a chest.

FIG. 2 RAO view showing a moderate stenosis.

FIG. 3 LAO view showing deployment of stent.

FIG. 4 LAO view post-stent placement. The stenosis had been reduced to 17%, the vessel remains patent with TIMI grade III flow.

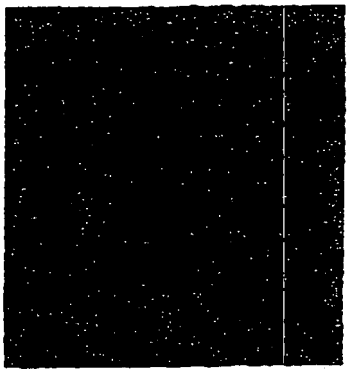


FIG. 5 RAO view of vessel at six month follow-up. The vessel remains patent with 25% residual stenosis.

PATIENT HISTORY

The patient was a 43 year old man with a history of smoking, hypertension and hypercholesterolemia who had no previous history of cardiac disease. He presented with a three month history of angina and had a positive exercise test with Canadian Heart Classification III pain.

CORONARY ANATOMY

The angiographic procedure revealed that the patient had multi-vessel disease with a right stenosis of 95%, measured at 71% on Quantitative Computer Analysis (QCA). The lesion lay on a bend of approximately 30° in the mid-course of a tortuous segment of the right coronary artery (RCA) with TIMI grade II flow. The lesion was eccentric and approximately 12mm in length. There were also further irregularities in the Left Anterior Descending (LAD) coronary artery.

PROCEDURE

PTCA to the right coronary artery was performed. An 8Fr ACS POWERCUBE™ JR4 was selected as guiding catheter. The lesion was crossed using a 0.014" ACS HIGH TORQUE FLOPPY™ guide wire and dilated twice using a 3.0mm ACS PRIME™ catheter to 4 atm for 60 seconds and 90 seconds. The residual stenosis was 30% with a moderate dissection and threatened closure. An ACS MULTI-LINK™ coronary stent system was chosen to repair this dissection. The stent, mounted on a 3.5mm balloon was deployed across the lesion using 7 atm pressure for 30 seconds. Using angiographic assessment, no further dilations were deemed necessary post-deployment of the stent.

RESULT

QCA measurements pre- and post-procedure showed a 71% stenosis had been dilated to a 17% stenosis. Angiographically the vessel lumen was clearly patent with TIMI grade III flow. The patient was treated with five days sub-cutaneous low molecular weight Heparin and commenced on Warfarin. The anti-coagulation was continued for 3 months and the patient remained on Aspirin, Dipyridamole and Beta Blocker until reviewed at 6 months.

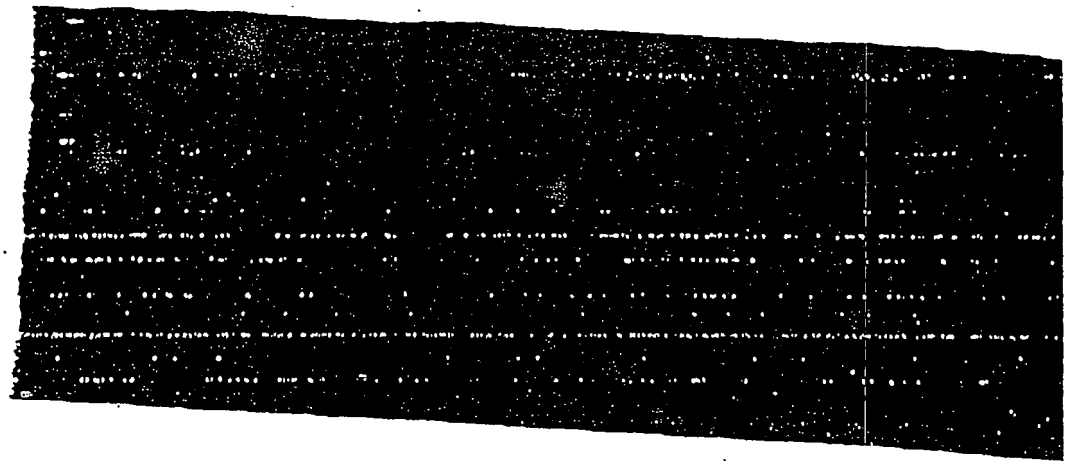
SIX MONTH FOLLOW-UP

There were no post-procedural complications. Six months angiographic follow-up revealed a 28% stenosis with a patent vessel lumen. The patient was free of angina, had TIMI grade III flow and rated Canadian Heart Classification I.

CASE SUMMARY

The successful outcome of this procedure was due to the key features of the ACS™ coronary stent system. The delivery system easily negotiated this patient's Shepherd's Crook, and, with it's flexible, retractable sleeve, well protected the stent as it manoeuvred through the tortuous anatomy to the dissection site. Accurate stent placement was aided by the double balloon markers. The durability, radial strength and conformability of the MULTI-LINK™ resulted in effective dissection repair with good long term follow-up.

ACS® thanks Drs. Ulrich Sigwart, Nigel Bailey, Jonathan Clague, and the staff of the Royal Brompton Hospital, London for this review.



1. [illegible]
2. [illegible]
3. [illegible]

2. [illegible]

3. [illegible]

4. [illegible]

5. [illegible]

   NOTE: [illegible]

DELIVERY AND DEPLOYMENT PROCEDURE

[illegible]

1. [illegible]

   NOTE: [illegible]

2. [illegible]

3. [illegible]

4. [illegible]

   NOTE: [illegible]

5. [illegible]

6. [illegible]

7. [illegible]

8. [illegible]

RETRIEVAL PROCEDURE

1. [illegible]

   NOTE: [illegible]

2. [illegible]

3. [illegible]

4. [illegible]

[illegible]

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

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[illegible]

[illegible]

[illegible]

[illegible]

PATENTS

[illegible]

GUIDANT

[illegible]

Graphical Symbols for Medical Device Labeling

STERILE EO

[illegible]

LOT

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

REF

[illegible]

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[illegible]

CE
0086

GUIDANT PPL2011832 (11/14/98)

ACS RX MULTI-LINK™

Coronary Stent System

CAUTION

[illegible]

STERILE. [illegible]

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DESCRIPTION

Stent. The ACS MULTI-LINK™ Stent [illegible]

ACS RX™ Delivery System. The ACS RX MULTI-LINK™ Coronary Stent System [illegible]

[illegible]

Table 1 provides the ACS RX MULTI-LINK™ Coronary Stent System [illegible]

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
3.0 x 15 mm	[illegible]	[illegible]	[illegible]	[illegible]
3.5 x 15 mm	[illegible]	[illegible]	[illegible]	[illegible]
4.0 x 15 mm	[illegible]	[illegible]	[illegible]	[illegible]
3.0 x 25 mm	[illegible]	7 atm	[illegible]	[illegible]
3.5 x 25 mm	[illegible]	7 atm	[illegible]	[illegible]
4.0 x 25 mm	[illegible]	7 atm	7 atm	[illegible]
3.0 x 35 mm	[illegible]	7 atm	[illegible]	[illegible]
3.5 x 35 mm	[illegible]	7 atm	[illegible]	[illegible]

Table 1 - ACS RX MULTI-LINK™ CORONARY STENT SYSTEM DEVICE SPECIFICATIONS

CONTENTS. 1 ACS RX MULTI-LINK™ Coronary Stent System

STORAGE. Store in a cool, dry, dark place.

INDICATIONS

The ACS RX MULTI-LINK™ Coronary Stent System [illegible]

CONTRAINDICATIONS

- [illegible]

WARNINGS

[illegible]

[illegible]

The ACS RX MULTI-LINK™ Coronary Stent System [illegible]

[illegible]

PRECAUTIONS

[illegible]

[illegible]

CLINICAL INFORMATION

[illegible]

[illegible]	12%
[illegible]	[illegible]
[illegible]	[illegible]
[illegible] MI	2%
[illegible] CABG	2%
[illegible] CABG	2%
[illegible]	0%
Death	0%

[illegible]

RECOMMENDED DRUG REGIMEN

[illegible]

MATERIALS REQUIRED FOR USE WITH THE ACS RX MULTI-LINK™ CORONARY STENT SYSTEM

[illegible]

INSPECTION PRIOR TO USE

[illegible]

PREPARATION OF THE ACS RX MULTI-LINK™ CORONARY STENT SYSTEM

[illegible] ACS RX MULTI-LINK™ Coronary Stent System [illegible]

1. [illegible]

US005421955A

United States Patent [19]

Lau et al.

[11] Patent Number: 5,421,955

[45] Date of Patent: Jun. 6, 1995

[54] EXPANDABLE STENTS AND METHOD FOR MAKING SAME

[75] Inventors: Lilip Lau, Cupertino; William M. Hartigan, Fremont; John J. Frantzen, San Jose, all of Calif.

[73] Assignee: Advanced Cardiovascular Systems, Inc., Santa Clara, Calif.

[21] Appl. No.: 214,402

[22] Filed: Mar. 17, 1994

Related U.S. Application Data

[63] Division of Ser. No. 164,986, Dec. 9, 1993, abandoned, which is a continuation of Ser. No. 781,518, Oct. 22, 1991, abandoned.

[51] Int. Cl.[6] B44C 1/22; C03F 1/02

[52] U.S. Cl. 216/48; 156/644; 156/654; 156/659.1; 604/95; 606/198

[58] Field of Search 156/643, 644, 654, 656, 156/659.1, 664; 604/95; 606/198

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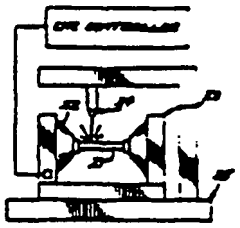
Primary Examiner—William Powell

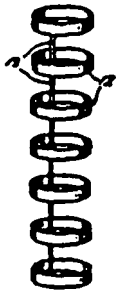
Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht

[57] ABSTRACT

The invention is directed to an expandable stent for implantation in a body lumen, such as an artery, and a method for making it from a single length of tubing. The stent consists of a plurality of radially expandable cylindrical elements generally aligned on a common axis and interconnected by one or more interconnective elements. The individual radially expandable cylindrical elements consist of ribbon-like material disposed in an undulating pattern. The stents are made by coating a length of tubing with an etchant-resistive material and then selectively removing portions of the coating to form a pattern for the stent on the tubing and to expose the portions of the tubing to be removed. This may done by machine-controlled activation and relative positioning of a laser in conjunction with the coated tubing. After the patterning of the tubing, the stent is formed by removing exposed portions of the tubing by an etching process.

15 Claims, 3 Drawing Sheets





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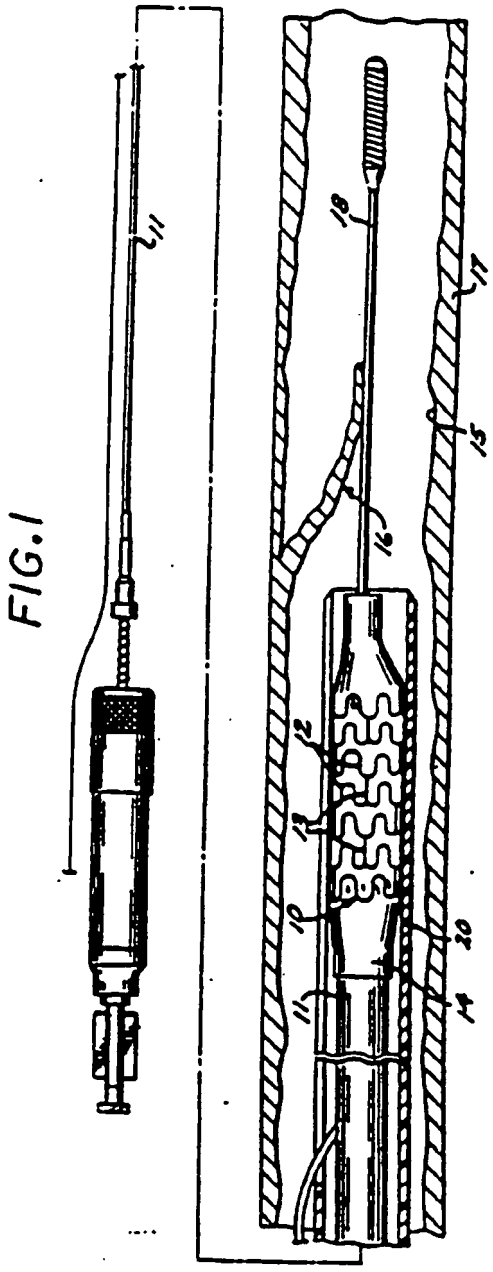


FIG. 1

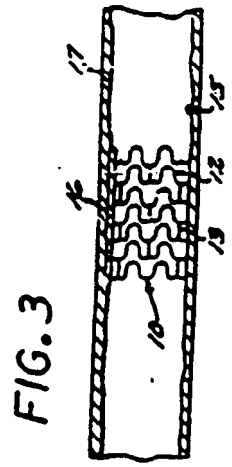


FIG. 3

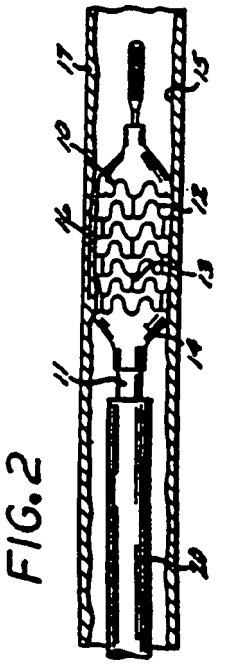


FIG. 2

FIG. 4

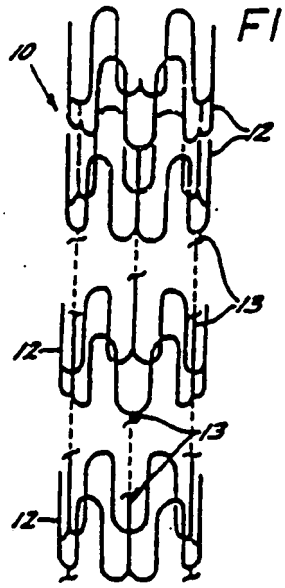


FIG. 6

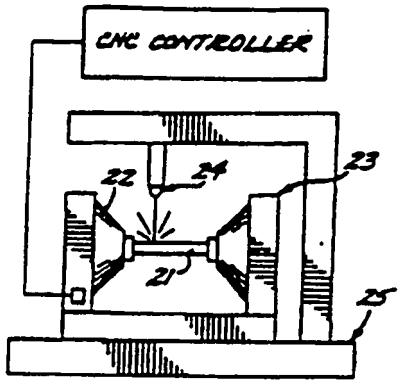


FIG. 5

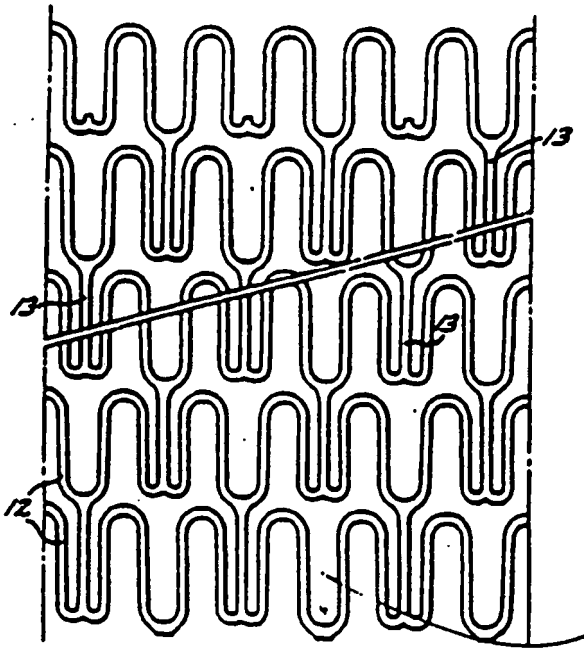


FIG. 7

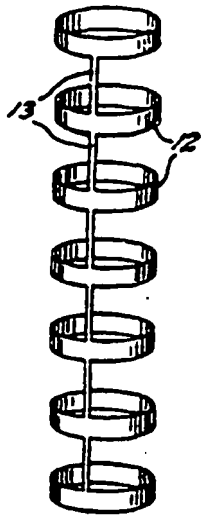


FIG. 8

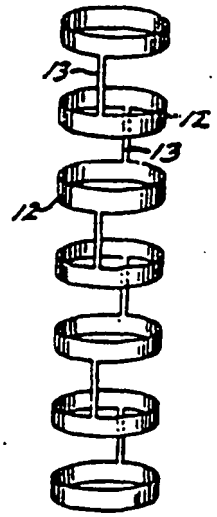


FIG. 9

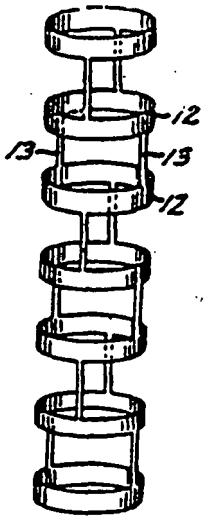


FIG. 10

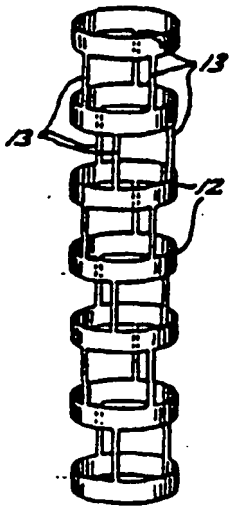
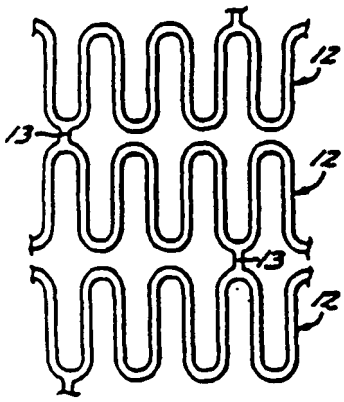


FIG. 11



EXPANDABLE STENTS AND METHOD FOR MAKING SAME

This application is a divisional application of Ser. No. 08/164,986, filed Dec. 9, 1993, now abandoned, which is a continuation of U.S. Ser. No. 07/783,356, filed Oct. 28, 1991, (now abandoned).

BACKGROUND OF THE INVENTION

This invention relates to expandable endoprosthesis devices, generally called stents, which are adapted to be implanted into a patient's body lumen, such as blood vessel, to maintain the patency thereof. These devices are very useful in the treatment of atherosclerotic stenosis in blood vessels.

Stents are generally tubular shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. They are particularly suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway therethrough.

Further details of prior art stents can be found in U.S. Pat. No. 3,868,956 (Alfidi et al.); U.S. Pat. No. 4,512,338 (Balko et al.); U.S. Pat. No. 4,553,545 (Maass et al.); U.S. Pat. No. 4,733,665 (Palmaz); U.S. Pat. No. 4,762,128 (Rosenbluth); U.S. Pat. No. 4,800,882 (Gianturco); U.S. Pat. No. 4,856,516 (Hillstead); and U.S. Pat. No. 4,886,062 (Wiktor), which are hereby incorporated herein in their entirety by reference thereto.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter. One of the difficulties encountered using prior stents involves maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery.

What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which it expands. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein.

The stent of the invention generally includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and are preferably positioned to prevent warping of the stent upon the expansion thereof.

The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so close as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but which is still very stiff in the radial direction in order to resist collapse.

The stent embodying features of the invention can be readily delivered to the desired lumenal location by mounting it on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stent to the expandable member on the catheter for delivery to the desired location are available. It is presently preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, or using bioresorbable temporary adhesives.

The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention generally have a circumferential undulating pattern, e.g. serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an aspect ratio of about two to one to about 0.5 to one (e.g., the ratio of the height to the width of an undulation). A one to one aspect ratio has been found particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern thereof similar to changes in a waveform which result from decreasing the waveform's amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded (except with NiTi alloys) so that the stent will remain in the expanded condition and, therefore, they must be sufficiently rigid when expanded to prevent the collapse thereof in use. With superelastic NiTi alloys, the expansion occurs when the stress of compression is removed so as to allow the phase transformation from austenite back to martensite and as a result the expansion of the stent.

The elongated elements or members which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed as a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical

elements which form the stent. In this manner there is no shortening of the stent upon expansion when measured from the outermost ends of the interconnecting members connected to the cylindrical elements at opposite ends of the stent.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site.

In a presently preferred embodiment of the invention the stent is conveniently and easily formed by coating stainless steel hypotubing with a material resistant to chemical etching, and then removing portions of the coating to expose portions of underlying tubing which are to be removed to develop the desired stent structure. The exposed portions of the tubing are removed by chemically etching from the tubing exterior leaving the coated portion of the tubing material in the desired pattern of the stent structure. The etching process develops smooth openings in the tubing wall without burrs or other artifacts which are characteristic of mechanical or laser machining processes in the small sized products contemplated. Moreover, a computer controlled laser patterning process to remove the chemical resistive coating makes photolithography technology adaptable to the manufacture of these small products. The forming of a mask in the extremely small sizes needed to make the small stents of the invention would be a most difficult task. A plurality of stents can be formed from one length of hypotubing by repeating the stent pattern and providing small webs or tabs to interconnect the stents. After the etching process, the stents can be separated by severing the small webs or tabs which connect them.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery.

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within an damaged artery, pressing the damaged lining against the arterial wall.

FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter.

FIG. 4 is a perspective view of a stent embodying features of the invention in an unexpanded state, with one end of the stent being shown in an exploded view illustrate the details thereof.

FIG. 5 is a plan view of a flattened section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. 4.

FIG. 6 is a schematic representation of equipment for selectively removing coating applied to tubing in the manufacturing of the stents of the present invention.

FIGS. 7 through 10 are perspective views schematically illustrating various configurations of interconnective element placement between the radially expandable cylindrical elements of the stent.

FIG. 11 is a plan view of a flattened section of a stent illustrating an alternate undulating pattern in the expandable cylindrical elements of the stent which are out of phase.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrate a stent 10 incorporating features of the invention which is mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 15. The artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter used for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20 as described in co-pending application Ser. No. 07/647,464, filed on Apr. 25, 1990 and entitled STENT DELIVERY SYSTEM may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevent abrasion of the body lumen by the open surface of the stent 10 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon.

Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g. tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10 onto the exterior of the balloon. The catheter-stent assembly is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed across the damaged arterial section with the detached or dissected lining 16 and then the catheter-stent assembly is advanced over a guidewire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15

is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of remote portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of stent 10 which are pressed into the wall of the artery 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 are preferably placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4 the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120 degrees apart. Each pair of interconnecting elements 13 on one end of a cylindrical element 12 are offset radially 60 degrees from the pair on the other side of the cylindrical element. The alternance of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible, and several examples are illustrated schematically in FIGS. 7-10. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion thereof.

FIG. 10 illustrates a stent of the present invention wherein three interconnecting elements 13 are disposed between radially expandable cylindrical elements 11. The interconnecting elements 13 are distributed radially around the circumference of the stent at a 120 degree spacing. Disposing four or more interconnecting elements 13 between adjacent cylindrical elements 12 will generally give rise to the same considerations discussed above for two and three interconnecting elements.

The properties of the stent 10 may also be varied by alteration of the undulating pattern of the cylindrical elements 12. FIG. 11 illustrates an alternative stent structure in which the cylindrical elements are in serpentine patterns but out of phase with adjacent cylindrical elements. The particular pattern and how many undulations per unit of length around the circumference of the cylindrical element 12, or the amplitude of the undulations, are chosen to fill particular mechanical requirements for the stent such as radial stiffness.

The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g. at the peaks of the undulations or along the sides of the undulations as shown in FIGS. 5 and 11.

The stent 10 of the present invention can be made in many ways. However, the preferred method of making the stent is to coat a thin-walled tubular member, such as stainless steel hypotubing, with a material which is resistive to chemical etchants, and then to remove portions of the coating to expose the underlying hypotubing which is to be removed but to leave coated portions of the hypotubing in the desired pattern for the stent so that subsequent etching will remove the exposed portions of the metallic tubing, but will leave relatively untouched the portions of the metallic tubing which are to form the stent. The coated portion of the metallic tube is in the desired shape for the stent. An etching process avoids the necessity of removing burrs or slag inherent in conventional or laser machining processes. It is preferred to remove the etchant-resistive material by means of a machine-controlled laser as illustrated schematically in FIG. 6.

A coating is applied to a length of tubing which, when cured, is resistive to chemical etchants. "Blue Photoresist" made by the Shipley Company in San Jose, Calif., is an example of suitable commercially available photolithographic coatings. The coating is preferably applied by electrophoretic deposition.

To ensure that the surface finish is reasonably uniform, one of the electrodes used for the electrochemical polishing is a doughnut-shaped electrode which is placed about the central portion of the tubular member.

The tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers. The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch in the unexpanded condition, the same outer diameter of the hypotubing from which it is made, and can be expanded to an outer diameter of 0.1 inch or more. The wall thickness of the hypotubing is about 0.003 inch. In the instance when the stent was plastic, it would have to be heated within the arterial site where the stent is expanded to facilitate the expansion of the stent. Once expanded, it is cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or by heating the balloon directly by a suitable system such as disclosed in application Ser. No. 07/521,337, filed Jan. 24, 1990, now U.S. Pat. No. 5,114,423, entitled "DILATATION CATHETER ASSEMBLY WITH HEATED BALLOON" which is incorporated herein in its entirety by reference. The stent may also be made of materials such as superelastic NiTi alloys such as described in application Ser. No. 07/629,381, filed Dec. 18, 1990, now abandoned, entitled SUPERELASTIC GUIDING MEMBER which is incorporated herein in its entirety by reference. In this case the stent would be formed full size but deformed (e.g. compressed) into a smaller diameter onto the balloon of the delivery catheter to facilitate transfer to a desired intraluminal site. The stress induced by the deformation transforms the stent from a martensite phase to a austenite phase and upon release of the force, when the stent reaches the desired intraluminal loca-

ness, allows the stent to expand due to the transformation back to the martensite phase.

Referring to FIG. 6, the coated tubing 21 is put in a rotatable collet fixture 22 of a machine controlled apparatus 23 for positioning the tubing 21 relative to a laser 24. According to machine-encoded instructions, the tubing 21 is rotated and moved longitudinally relative to the laser 24 which is also machine controlled. The laser selectively removes the etchant-resistive coating on the tubing by ablation and a pattern is formed such that the surface of the tube that is to be removed by a subsequent chemical etching process is exposed. The surface of the tube is therefore left coated in the discrete pattern of the finished stent.

A presently preferred system for removing the coating on the tubing includes the use of an 80 watt CO_2 laser, such as a Coherent Model 44, in pulse mode (0.3 mS pulse length); 48 mA. key current and 48 W key power with 0.75 W average power, at 100 Hz. Anorad FR = 20; 12.5 Torr; with no assist gas. Low pressure air is directed through the fine focus head to ensure that no vapor contacts the lens. The assist gas jet assembly on the laser unit may be removed to allow a closer proximity of the fine focus head and the collet fixture. Optimum focus is set at the surface of the tubing. Cured photoresist coating readily absorbs the energy of the CO_2 wavelength, so that it can be readily removed by the laser. A coated 4 inch length of 0.06 inch stainless steel tubing is preferred and four stents can be patterned on the length of tubing. Three tabs or webs between stents provide good handling characteristics for the tubing after the etching process.

The process of patterning the resistive coating on the stent is automated except for loading and unloading the length of tubing. Referring again to FIG. 6 it may be done, for example, using a CNC opposing collet fixture 22 for axial rotation of the length of tubing, in conjunction with a CNC X-Y table 25 to move the length of tubing axially relative to a machine controlled laser as described. The entire space between collets can be patterned using the CO_2 laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating, but is otherwise conventional.

This process makes possible the application of present photolithography technology in manufacturing the stents. While there is presently no practical way to mask and expose a tubular photoresist-coated part of the small size required for making intravascular stents, the foregoing steps eliminate the need for conventional masking techniques.

After the coating is thus selectively ablated, the tubing is removed from the collet fixture 22. Next, wax such as ThermoCote N-4 is heated to preferably just above its melting point, and inserted into the tubing under vacuum or pressure. After the wax has solidified upon cooling, it is refrigerated below its melting point to allow softening, and a smaller diameter stainless steel shaft is inserted into the softened wax to provide support. The tubing is then etched chemically in a conventional manner. After etching the tabs connecting the stents any surface roughness or debris from the tube is removed. The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO CO., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110–135 degrees F. and the current density is about 0.4 to about 1.5 amps per in.^{2} Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications and improvements can be made without departing from the scope of the invention.

What is claimed is:

1. The process of making a stent which includes the steps of:

a) applying a coating resistive to chemical etching to a length of tubing;

b) selectively removing portions of the resistive coating to expose sections of the tubing; and

c) removing exposed portions of the tubing.

2. The process of claim 1, wherein a plurality of stents are made from a single piece of tubing.

3. The process of claim 1, wherein the stent is made from a biocompatible material selected from the group consisting of polymers, stainless steel, titanium, superelastic NiTi alloys and tantalum.

4. The process of claim 1, wherein the coating is applied by electrophoretic deposition.

5. A method for making an open reticulated tubular structure, comprising the steps of:

a) providing a discrete length of thin walled tubing;

b) forming a resistive coating onto the exterior of the tubing;

c) selectively removing portions of the resistive coating on the exterior of the tubing to leave the desired pattern of the complete open reticulated tubular structure coated with resistive coating and to expose portion of the tubing to be removed; and

d) removing the exposed portions of the tubing.

6. The method of claim 5 wherein the exposed portions of the tubing is removed by etching.

7. The method of claim 5 wherein the selective removal of the resistive coating is accomplished by machine controlled relative movement of the tubing and laser.

8. The method of claim 5 wherein the laser used to selectively remove the resistive coating emits a particular wavelength of light which is readily absorbable by said coating.

9. The method of claim 5 wherein the laser is a CO_2 gas laser.

10. The method of claim 5 wherein the resistive coating used is a photolithographic chemically resistive coating.

11. A kit comprising:

a) an elongated stent delivery catheter having proximal and distal extremities, and an expandable member on the distal extremity; and

b) a longitudinally flexible stent which is adapted to be slidably mounted onto the expandable member of said catheter and which comprising a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected to as to be generally aligned on a common axis.

12. A stent delivery system comprising:

an elongated stent delivery catheter having proximal and distal extremities, and an expandable member on the distal extremity; and

a longitudinally flexible stent which is adapted to be slidably mounted onto the expandable member of said catheter and which comprises a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common axis.

13. A method for making a pattern in an intravascular stent comprising the steps of:

providing a discrete length of thin-walled hypotube;

applying a resistive coating on to the exterior of at least a portion of said hypotube;

means for selectively removing portions of the resistive coating from the exterior of said hypotube;

applying a chemical etchant to said hypotube so that said chemical etchant removes those portions of said hypotube where said resistive coating has been removed; and

removing the remaining resistive coating to provide an intravascular stent having a distinctive pattern.

14. The method for making the intravascular stent of claim 13, wherein said means for selectively removing said resistive coating is by a machine controlled laser.

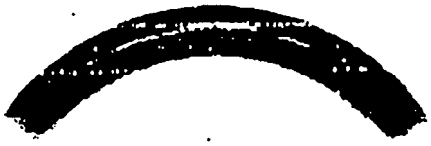
15. The method for making the intravascular stent of claim 14, wherein said laser is a CO_2 gas laser operating in a pulsed mode.

* * * * *

Stent Implantation Procedure

STENT 1

The ACS MULTI-LINK stent is a small, latticed stainless steel tube which is introduced into the coronary artery on a balloon catheter.



STENT 2

The ACS MULTI-LINK(tm) Coronary Stent System is manuevered into the blocked artery. The balloon is then inflated causing the stent to expand, pressing it against the vessel wall.

STENT 3

Once the balloon has been deflated and withdrawn, the ACS MULTI-LINK stent stays in place permanently - holding the blood vessel open, improving the flow of blood and relieving the symptoms of coronary artery disease

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Guidant's ACS MULTI-LINK(tm) Coronary Stent System Receives Rapid Approval for U.S. Market Release by FDA

Indianapolis, IN -- October 2, 1997 -- Guidant Corporation (NYSE and PCX: GDT), a world leader in the treatment of coronary artery disease, today announced that the ACS MULTI-LINK(Coronary Stent System has been approved by the U.S. Food and Drug Administration (FDA) for marketing in the U S and is available for immediate shipment. The FDA marketing approval came just 113 days after Guidant electronically filed its pre-market approval application in June. The ACS MULTI-LINK stent is the first of a new generation of stents, and the only stent approved for use in de novo (first time) and restenotic (re-closed) arteries. Its design, from a single stainless steel tube, without welds or gaps, provides the scaffolding necessary to hold the artery open ensuring blood flow to the heart. Coronary stenting is an alternative procedure to angioplasty and has been shown to more effectively keep the artery open.

The FDA based their approval on the results of a randomized clinical trial in the United States and Canada involving more than 1,300 patients at 59 clinical investigational centers. This randomized trial, the ACS Stent Clinical Equivalence in de Novo Lesions Trial (ASCENT), was a multi-center study designed to show equivalency of the ACS MULTI-LINK stent to the leading stent in the U.S. The ASCENT trial not only showed equivalence but it also demonstrated a statistically significant improvement in 30-day survival rates and showed a favorable trend toward improvement in all other clinical measurements. Data from this trial will be submitted to peer-reviewed journals and a more thorough discussion of the results will be provided at the time of publication. "The extensive clinical data and well run study with cooperation from approximately 220 physician investigators enabled the FDA to quickly understand the safety and efficacy profile of the product," stated Don Baim, M.D., Beth Israel/Deaconess Hospital, Boston, MA, principal investigator for the ASCENT trial. "Clinically, the ACS MULTI-LINK stent sets a new standard for stents."

"The ACS MULTI-LINK stent was designed specifically with the patient in mind. It is engineered with a unique combination of radial strength and flexibility," said Ginger Howard, president of Guidant's Vascular Intervention Group. "In addition, the stent is mounted on a very easy-to-use delivery system that provides 15mm and 25mm lengths so the physician can better match the stent to the length of the blockage."

Guidant will market the ACS MULTI-LINK stent on the Rapid Exchange (RX) platform, complemented by other products such as the ACS RX COMET(tm) Coronary Dilatation Catheter, ACS HI-TORQUE BALANCE MIDDLEWEIGHT(tm) Guide Wire, and the ACS TOURGUIDE II(tm) Guiding Catheter. RX systems are easier to use, allowing physicians to shorten procedure time and use less x-ray. With immediate availability of the ACS MULTI-LINK stent system, Guidant is providing an extensive physician training program as well as training for hospital staff to ensure appropriate product use.

The ACS MULTI-LINK stent has been available in Europe since November 1995 and was approved by the Japanese Ministry of Health and Welfare in June 1997, with reimbursement approval expected later this year. To date, more than 95,000 ACS MULTI-LINK stents have been sold worldwide, making this stent a current market leader.

A leader in the medical device industry, Guidant provides innovative, cost-effective products and services to the global cardiology and minimally invasive surgery marketplaces.

For more information about Guidant's products and services, visit the company's Web site at *http://www.guidant.com.*

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INFRINGEMENT OF THE '762 PATENT BY THE ACS MULTI-LINK STENT

'762 Claim 13	ACS Multi-Link
An expandable intraluminal vascular graft, comprising:	
a thin-walled tubular member having first and second ends	See "A" (thin-walled tubular member) and "B" (first and second ends).
and a wall surface disposed between the first and second ends,	See "C".
the wall surface having a substantially uniform thickness	See "D".
and a plurality of slots formed therein,	See "E".
the slots being disposed substantially parallel to the longitudinal axis of the tubular member;	See "E".
the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and	See "F".
the tubular member having a second, expanded and deformed diameter,	See "G".
upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member,	
whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway	

INFRINGEMENT OF THE '762 PATENT BY THE ACS MULTI-LINK STENT

'762 Claim 23	ACS Multi-Link
The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.	See "C".

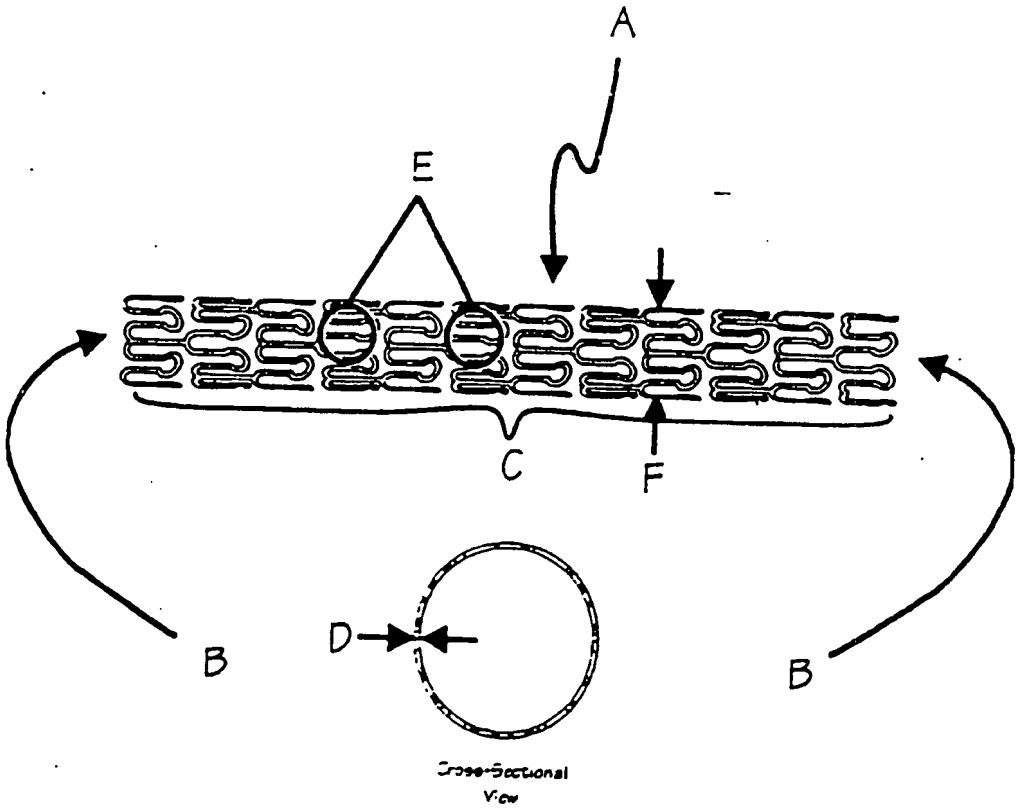
INFRINGEMENT OF THE '762 PATENT BY THE ACS MULTI-LINK STENT

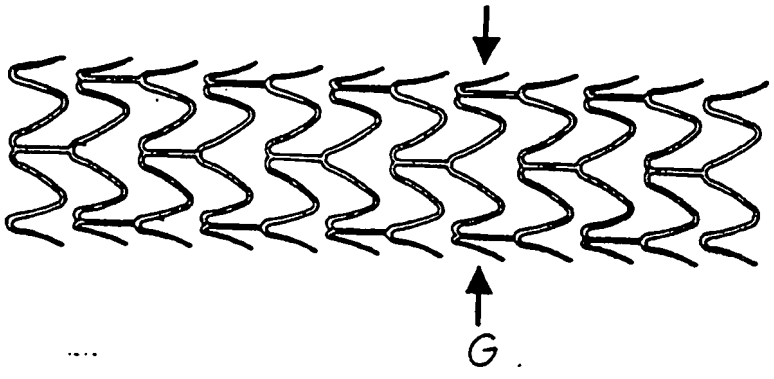
'762 Claim 24	ACS Multi-Link
An expandable prosthesis for a body passageway, comprising:	
a thin-walled tubular member having first and second ends	See "A" (thin-walled tubular member) and "B" (first and second ends).
and a wall surface disposed between the first and second ends,	See "C".
the wall surface having a substantially uniform thickness	See "D".
and a plurality of slots formed therein,	See "E".
the slots being disposed substantially parallel to the longitudinal axis of the tubular member;	See "E".
the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen, and	See "F".
the tubular member having a second, expanded and deformed diameter,	See "G".
upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member,	
whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway	

INFRINGEMENT OF THE '762 PATENT BY THE ACS MULTI-LINK STENT

'762 Claim 34	ACS Multi-Link
The expandable prosthesis of claim 24,	
wherein the outside of the wall surface, of the tubular member is a smooth surface, when the tubular member has the first diameter.	See "C".

INFRINGEMENT OF THE '762 PATENT BY THE ACS MULTI-LINK STENT





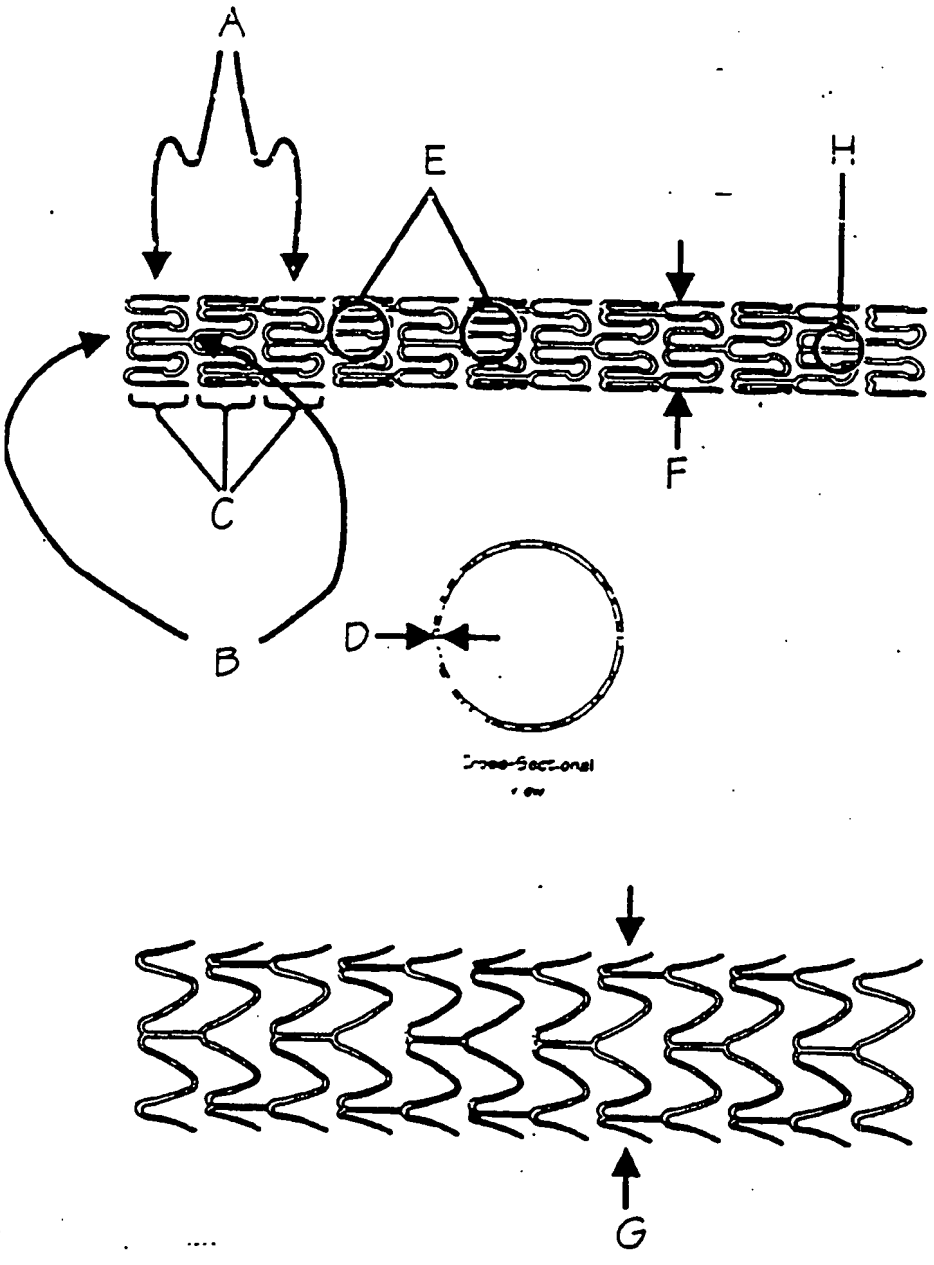
INFRINGEMENT OF THE '417 PATENT BY THE ACS MULTI-LINK STENT

'417 Claim 25	ACS MULTI-LINK
An expandable intraluminal vascular graft, comprising:	
a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends,	See "A" (thin-walled tubular members), "B" (first and second ends) and "C" (wall surface).
the wall surface having a substantially uniform thickness and	See "D".
a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;	See "E".
at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;	See "H".
each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and	See "F".
the tubular members having a second, expanded and deformed diameter,	See "G".
upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members,	
whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.	

INFRINGEMENT OF THE '417 PATENT BY THE ACS MULTI-LINK STENT

'417 Claim 29	ACS MULTI-LINK
An expandable prosthesis for a body passageway, comprising:	
a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends,	See "A" (thin-walled tubular member), "B" (first and second ends) and "C" (wall surface).
the wall surface having a substantially uniform thickness and	See "D".
a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;	See "E".
at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;	See "H".
each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and	See "F".
the tubular members having a second, expanded and deformed diameter,	See "G".
upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members,	
whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.	

INFRINGEMENT OF THE '417 PATENT BY THE ACS MULTI-LINK STENT



CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of October, 1997 the attached **DECLARATION OF LEE P. BENDEL** was served upon the defendants at the address and in the manner indicated below:

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US005102417A

United States Patent [19]

Palmaz

[11] Patent Number: 5,102,417

[45] Date of Patent: Apr. 7, 1992

[54] EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

[75] Inventor: Julio C. Palmaz, San Antonio, Tex.

[73] Assignee: Expandable Grafts Partnership, San Antonio, Tex.

[21] Appl. No.: 174,246

[22] Filed: Mar. 28, 1988

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 923,798, Nov. 3, 1986, Pat. No. 4,739,762, which is a continuation-in-part of Ser. No. 796,009, Nov. 7, 1985, Pat. No. 4,733,665.

[51] Int. Cl.[5] A61M 5/00; A61F 2/02

[52] U.S. Cl. 606/195; 604/8; 604/96; 604/282; 623/11

[58] Field of Search 128/343, 344; 604/93, 604/49, 282, 343, 97, 8, 283; 623/1, 12, 11; 606/191-195, 108

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Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Mark Bockelman
Attorney, Agent, or Firm—Ben D. Tobor

[57] ABSTRACT

A plurality of expandable and deformable intraluminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The grafts may be thin-walled tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members, and adjacent grafts are flexibly connected by at least one connector member.

36 Claims, 3 Drawing Sheets

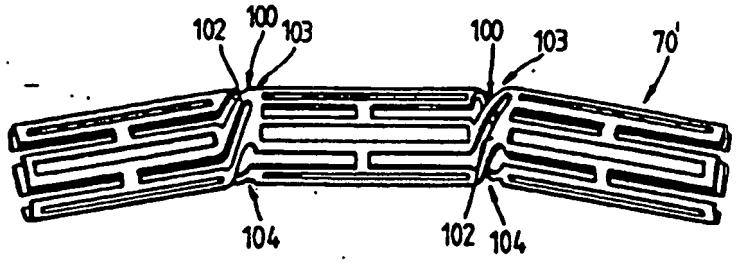


FIG.2

FIG.1B

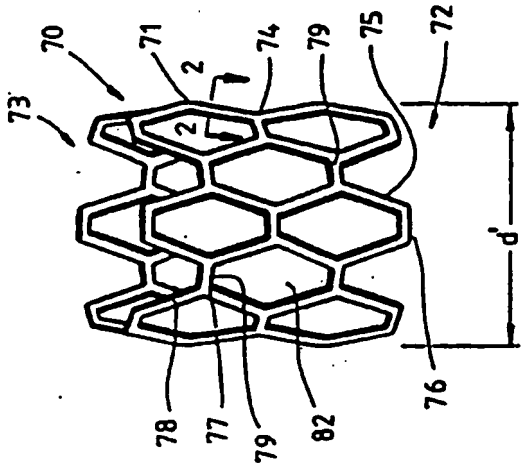


FIG.1A

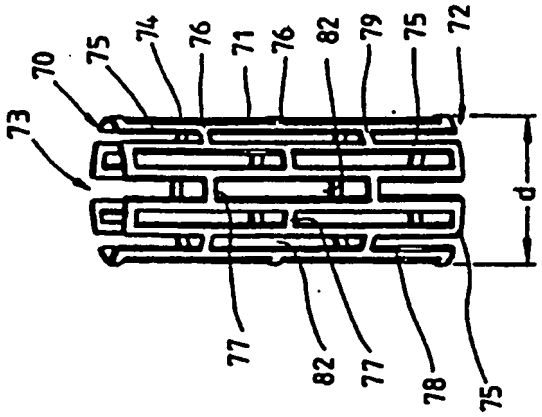
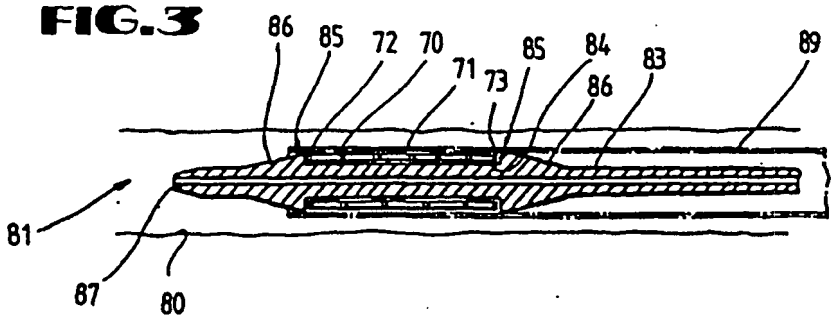


FIG.3



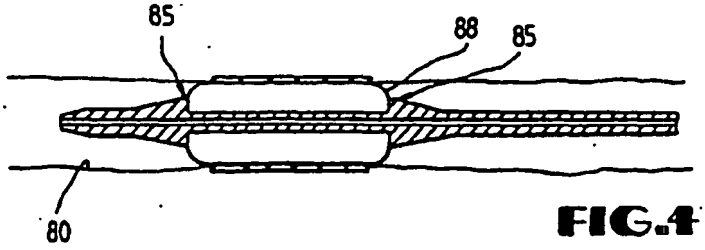
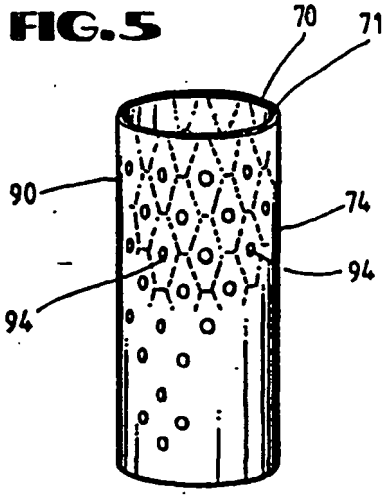


FIG.4

FIG.5



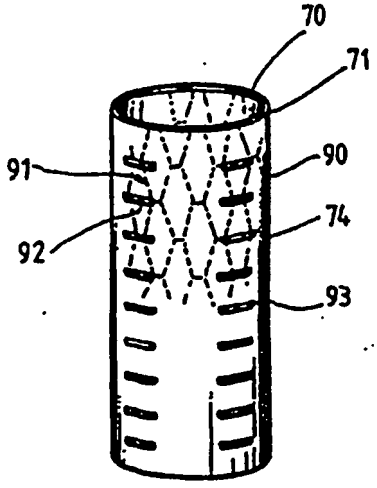


FIG.6

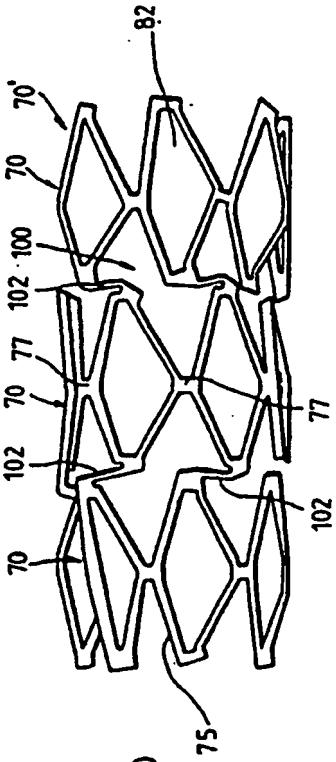


FIG.10

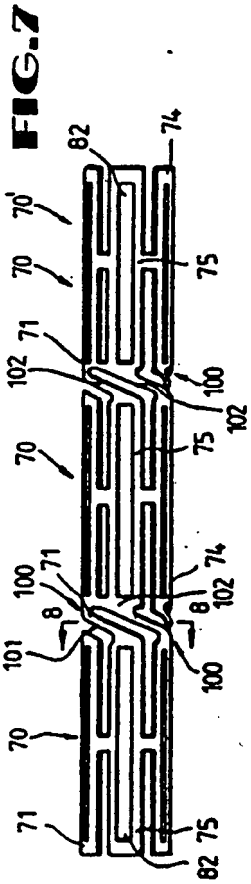


FIG.7

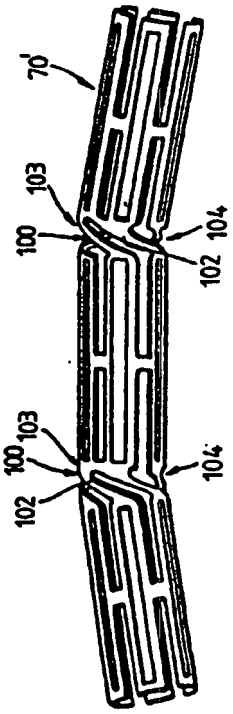


FIG.9

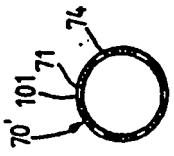


FIG.8

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part application of Applicant's co-pending application, Ser. No. 923,798 now U.S. Pat. No. 4,739,762, filed Nov. 3, 1986, which application is a continuation-in-part of Applicant's co-pending application, Ser. No. 06,796,009 now U.S. Pat. No. 4,733,665 filed Nov. 7, 1985, entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that

the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty

of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

For repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway through which the graft is passed by the catheter. In other words, in many instances, it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location and prevents rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a plurality of thin-walled tubular members having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; each tubular member having a first diameter which permits intraluminal delivery of the thin-walled tubular members into a body passageway having a lumen; and the tubular members having a second, expanded diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular shaped members may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Another feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members. An additional feature of the present invention is that at least one connector member may be a thin-walled, spiral member, coplanar with adjacent tubular members.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a plurality of prostheses within a body passageway. The method of the present invention comprises the steps of: disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other; disposing a plurality of connected prostheses upon a catheter; inserting the prostheses and catheter within the body passageway by catheterization of the body passageway; and providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prostheses with a force in excess of the elastic limit of the portion of the at least one prostheses, to implant the prostheses within the body passageway.

A further feature of the present invention is that the portion of the catheter in contact with the prostheses may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that a thin-walled tubular member may be utilized as each prosthesis, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member. Another feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one elongate member is formed between adjacent slots.

Another feature of the present invention is that the at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent prostheses. A further feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular member. A further feature of the present invention is that the at least one connector member may be formed as a thin-walled, spiral member, coplanar with adjacent tubular members.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prostheses on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prostheses.

The expandable intraluminal vascular graft, method for implanting a plurality of prostheses within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; permits expansion of the graft to a variable size dependent upon conditions within the body passageway; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2—2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B;

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;

FIG. 7 is a front view of another embodiment of a graft or prosthesis in accordance with the present invention;

FIG. 8 is a cross-sectional view of the graft, taken along line 8—8 of FIG. 7.

FIG. 9 is a perspective view of the graft of FIG. 7, wherein the graft has been bent or articulated; and

FIG. 10 is a perspective view of the graft of FIG. 7, after the graft has been expanded and deformed.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of catheter created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and

dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

The foregoing described construction of graft, or prosthesis, 70 permits graft, or prosthesis, 70 to be expanded uniformly, and outwardly, in a controlled manner into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prosthesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prothesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prosthesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prothesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prothesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prothesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any out-

ward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, or prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then controllably expanded and deformed by controllably expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon TM sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is, controllably expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4, and by the amount of expansion of the inflatable portion 84 of catheter 83. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80, in excess of that required to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid,

multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert or biologically compatible coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM , or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area. Examples of biologically compatible coatings 90 would include coatings made of absorbable polymers such as those used to manufcture absorbable sutures. Such absorbable polymers include polyglycoides, polylacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating 90 is absorbed, or dissolves, the drug would be slowly released into the body passageway 80.

Turning now to FIGS. 7–10, an expandable intraluminal vascular graft, or prosthesis, 70' is shown for implantation in curved body passageways 80, or for use in elongated sections of body passageway 80, when a prosthesis, or graft, 70' is required which is longer than the grafts, or prostheses, 70 of FIG. 1A. Identical reference numerals are used throughout FIGS. 7–10 for elements which are the same in design, construction, and operation, as those previously described in connection with FIGS. 1A–6, and primed reference numerals are used for elements which are similar in construction, design, and operation, as those previously described in connection with FIGS. 1A–6.

As seen in FIG. 7, graft, or prosthesis, 70' generally includes a plurality of prostheses, or grafts 70 as described previously in connection with FIGS. 1A, 1B, and 2. Preferably, the length of each graft, or prosthesis, 70 is approximately the length of one slot 82; however, the length of each graft 70 could be approximately equal to the length of two slots 82, as illustrated in FIG. 1A. Disposed between adjacent tubular members, 71, or adjacent grafts, or prostheses, 70, is at least one connector member 100 to flexibly connect adjacent tubular members 71, or grafts, or prostheses, 70. Connector member, or members, 100 are preferably formed of the same materials as grafts 70, as previously described, and connector members 100 may be formed integrally between adjacent grafts 70, or tubular members, 71 as shown in FIG. 7. As seen in FIG. 8, the cross-sectional configuration of connector member, or members, 100, along the longitudinal axis of graft, or prosthesis 70', is the same, in that connector member, or members, 100 have the same uniform wall thickness of elongate members 75. Of course, it should be readily apparent to one of ordinary skill in the art, that the thickness of connector members 100 could alternatively be smaller than that of elongate members 75; however, it is preferable that the outer circumferential surface 101 of connector members 100 lies in the same plane formed by the wall surface 74 of grafts, or prostheses 70, as seen in FIG. 8.

Still with reference to FIGS. 7–8, connector members 100 are preferably disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent grafts, or prostheses, 70. Further, it is preferable that the at least one connector member 100 is formed as a thin-walled spiral member 102 which is coplanar with the outer wall surface 74 of the adjacent tubular members 71, or adjacent grafts, or prostheses, 70. It should be noted that although graft, or prosthesis, 70' is illustrated as including three grafts, or prostheses, 70 flexibly connected to one another by connector members 100, as few as two grafts 70 could be connected to form graft, or prosthesis, 70'. Furthermore, many grafts 70 could be flexibly connected by connector members 100 as are desired to form graft, or prosthesis, 70'.

The delivery and expansion of graft or prosthesis, 70' is the same as that previously described in connection with FIGS. 1A, 1B, and 3–4. The length of the expandable, inflatable portion 84 of catheter 83 would be sized to conform with the length of graft, or prosthesis, 70,, as should be readily apparent to one of ordinary skill in the art. Except for the length of the expandable, inflatable portion 84 of catheter 83, the method of delivery of graft, or prosthesis, 70' and its subsequent, controllable expansion and deformation is the same as previously described.

With reference to FIG. 9, the prosthesis 70' is illustrated in the configuration it would assume when being delivered to the desired location within the body passageway 80 and the graft, or prosthesis, 70' is disposed upon catheter 83 and is passing through a curved portion of body passageway 80, such as an arterial bend. For clarity, catheter 83 is not shown in FIG. 9, since the flexibility of such catheters 83 is well known in the art. As seen in FIG. 9, because of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prostheses, 70, graft, or prosthesis, 70' is able to flexibly bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways 80. As seen in FIG. 9, as graft, or prosthesis, 70' bends, or articulates about the longitudinal axis of graft 70', the spacing between tubular members 71 increases, or expands, about the outer side of the curve, or bend, 103; and the spacing decreases, or is compressed, on the inner side of the curve, or bend, 104. Likewise, spiral connector members 102 adjacent the outer side of the curve 103 flexibly and resiliently stretch to permit the expansion of the spacing thereat; and the spiral connector members 102 adjacent the inner side of the curve, 104 flexibly and resiliently compress to permit the decrease in the spacing between tubular members 71 on the inner side of curve 104. It should be noted that connector members 100 permit the bending, or articulation, of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70'.

Turning now to FIG. 10, graft, or prosthesis, 70' is illustrated in its expanded, and deformed configuration, similar to that illustrated in FIG. 1B. It should be noted that should it be desired to implant graft, or prosthesis, 70' on a curved portion of a body passageway 80, such

implantation and expansion would be permitted by the connector members 100. It should also be noted that prostheses, or grafts, 70 could be flexibly connected to one another to form a graft, or prosthesis, 70' wherein such grafts, or prostheses, 70 are formed as wire mesh tubes of the type illustrated in Applicant's co-pending application, Ser. No. 06/796,009, filed Nov. 7, 1985, entitled, "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft", which application is incorporated by reference herein.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials, or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

What is claimed is:

1. A method for implanting a plurality of prostheses within a body passageway comprising the steps of:

disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other;

disposing the plurality of connected prostheses upon a catheter;

inserting the prostheses and catheter within the body passageway by catheterization of said body passageway; and

providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prosthesis with a force in excess of the elastic limit of the portion of the at least one prosthesis, to implant the prostheses within the body passageway.

2. The method of claim 1, further including the steps of: collapsing the portion of the catheter associated with the prostheses, and removing the catheter from the body passageway.

3. The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.

5. The method of claim 1, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axis of adjacent prostheses.

6. The method of claim 1, including the step of: utilizing a wire mesh tube as each prosthesis, the wire mesh tubes having a first predetermined collapsed diameter which permits the tubes to be disposed upon the catheter and inserted into the body passageway.

7. The method of claim 6, including the step of disposing the at least one connector member coplanar with each wire mesh tube and non-parallel to the longitudinal axis of the wire mesh tubes.

8. The method of claim 6, wherein tantalum is utilized for the wire mesh tube.

9. The method of claim 1, wherein a thin-walled, tubular member is utilized as each prosthesis, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member.

10. The method of claim 9, wherein tantalum is utilized for the tubular member.

11. The method of claim 9, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one elongate member is formed between adjacent slots.

12. The method of claim 11, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

13. The method of claim 9, wherein each thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby each expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of each thin-walled tubular member does not cause a rupture of the body passageway.

14. The method of claim 13, wherein each thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

15. The method of claim 9, including the step of disposing the at least one connector member coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

16. The method of claim 9, including the step of forming the at least one connector member as a thin-walled spiral member, coplanar with adjacent tubular members.

17. A method for expanding the lumen of a body passageway comprising the steps of:

connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts;

inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway; and

expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway, by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the intraluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal rafts remain in the passageway.

18. The method of claim 17, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axis of the intraluminal grafts.

19. The method of claim 17, including the step of: utilizing a wire mesh tube as the intraluminal graft, the wire mesh tube having a first predetermined, collapsed diameter which permits the tube to be inserted within the body passageway at the desired location.

20. The method of claim 19, including the step of disposing the at least one connector member coplanar with each wire mesh tube and non-parallel to the longitudinal axis of the wire mesh tubes.

21. The method of claim 19, wherein tantalum is utilized for the wire mesh tube.

22. The method of claim 17, wherein a thin-walled tubular member is utilized as each intraluminal graft, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular members.

23. The method of claim 22, including the step of disposing the at least one connector member coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

24. The method of claim 22, including the step of forming the at least one connector member as a thin-walled spiral member, coplanar with adjacent tubular members.

25. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

26. The expandable intraluminal graft of claim 25, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

27. The expandable intraluminal graft of claim 25, wherein the at least one connector member is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

28. The expandable intraluminal graft of claim 25, wherein the at least one connector member is a thin-walled, spiral member, coplanar with adjacent tubular members.

29. An expandable prosthesis for a body passageway, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

30. The expandable prosthesis of claim 29, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

31. The expandable prosthesis of claim 29, wherein the at least one connector member is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

32. The expandable prosthesis of claim 29, wherein the at least one connector member is a thin-walled, spiral member, coplanar with adjacent tubular members.

33. An apparatus for intraluminally reinforcing a body passageway, comprising:

a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prostheses on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway.

34. The apparatus of claim 33, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent the ends of the expandable, tubular prostheses.

35. An apparatus for expanding the lumen of a body passageway comprising:

a plurality of expandable and deformable thin-walled intraluminal vascular grafts, each graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the grafts, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular grafts on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular grafts are expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim 35, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent the ends of the expandable intraluminal vascular grafts.

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